



**Stem CELL Transplant  
for primary Immune Deficiencies in Europe**

**INITIAL REPORT**

*Data from HSCT to 6 months post-HSCT*

Chairman

ESID BMT-Gene therapy WP  
& EBMT-IEWP

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## INITIAL REPORT OF HAEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT)

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Date of this report

__	__	__	__	__	__	__	__	__	__
day			month			year			

**SCETIDE Patient Number**

__	__	__	__	__	__	__	__
----	----	----	----	----	----	----	----

ESID Patient Number

__	__	__	__	__	__	__	__
----	----	----	----	----	----	----	----

EBMT Patient Number (UIC)

__	__	__	__	__	__	__	__	__	__	__	__	__	__
----	----	----	----	----	----	----	----	----	----	----	----	----	----

## I - CENTRE

Centre Identification Number

__	__	__	__	__	__
----	----	----	----	----	----

Name of the Institution .....

Referring physician .....

Address .....

.....

.....

.....

Phone number .....

Fax number .....

E-mail .....

Data manager .....

Phone number .....

E-mail .....

## II - PATIENT

Family name (*initial*) .....

First name (*initial*) .....

**Sex** Male ☐ Female ☐

**Date of Birth**

__	__	__	__	__	__	__	__	__	__
day			month			year			

Date of this HSCT 

__	__	__	__	__	__	__	__	__	__
day			month			year			

Number of HSCT(s) previously performed .....

| | | | | | | | | |  
 day month year



Yes |\_\_\_| No |\_\_\_| unknown |\_\_\_|

\* for X-linked disease, use allele 1 only

Yes |\_\_\_| No |\_\_\_| unknown |\_\_\_|

## IV - DISEASE STATUS PRIOR TO HSCT

① Disease status should be assessed before start of conditioning, please give values from the same time point (from 2 to 4 weeks before HSCT)

### A- HAEMATOLOGICAL VALUES BEFORE CONDITIONING

White blood cell count ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_|

Granulocytes ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_|

Hemoglobin (g/dL) |\_|\_|\_|\_|\_|\_|\_|\_|

Platelets ( $\times 10^9/L$ ) (non transfused values) |\_|\_|\_|\_|\_|\_|\_|\_|

Number of red cells transfusions prior to HSCT

0 |\_| 1-10 |\_| 11-50 |\_| >50 |\_| unknown |\_|

Number of platelets transfusions prior to HSCT

0 |\_| 1-10 |\_| 11-50 |\_| >50 |\_| unknown |\_|

Number of granulocyte transfusions prior to HSCT

0 |\_| 1-10 |\_| 11-50 |\_| >50 |\_| unknown |\_|

### B- IMMUNOLOGICAL VALUES BEFORE CONDITIONING

Lymphocyte count (mean of several counts) ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_|

Total T cells (CD3) ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_| or (%) |\_|\_|\_|\_|

CD4 ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_| or (%) |\_|\_|\_|\_|

Naive CD4 e.g. CCR7+ or CD31+CD45RA+/CD4 Tcells (%) |\_|\_|\_|\_|

CD8 ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_| or (%) |\_|\_|\_|\_|

Naive CD8 e.g. CCR7+CD45RA+/CD8 Tcells (%) |\_|\_|\_|\_|

Total B cells (CD19) ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_| or (%) |\_|\_|\_|\_|

NK cells e.g. CD16+56+/NKp43 ( $\times 10^9/L$ ) |\_|\_|\_|\_|\_|\_|\_|\_| or (%) |\_|\_|\_|\_|

Lectin/Mitogen induced lymphocyte proliferation

Absent |\_| Decreased |\_| Normal or increased |\_| not done |\_| unknown |\_|

Antigen induced proliferation

Absent |\_| Decreased |\_| Normal or increased |\_| not done |\_| unknown |\_|

Did the recipient receive Ig? Yes |\_| No |\_| unknown |\_|

Serum IgG (g/L) |\_|\_|\_|\_|\_|\_|\_|\_|

Absent |\_| Low |\_| Normal or high |\_| not done |\_| unknown |\_|

Serum IgA (g/L) |\_|\_|\_|\_|\_|\_|\_|\_|

Absent |\_| Low |\_| Normal or high |\_| not done |\_| unknown |\_|

Serum IgM (g/L) |\_|\_|\_|\_|\_|\_|\_|\_|

Absent |\_| Low |\_| Normal or high |\_| not done |\_| unknown |\_|

Serum IgE (kUI/L) |\_|\_|\_|\_|\_|\_|\_|\_|

Absent |\_| Low |\_| Normal or high |\_| not done |\_| unknown |\_|

### Antibody response

Tetanus	Absent <input type="checkbox"/>	Decreased <input type="checkbox"/>	Normal or increased <input type="checkbox"/>	not done <input type="checkbox"/>	unknown <input type="checkbox"/>
Diphtheria	Absent <input type="checkbox"/>	Decreased <input type="checkbox"/>	Normal or increased <input type="checkbox"/>	not done <input type="checkbox"/>	unknown <input type="checkbox"/>
Haemophilus Influenzae	Absent <input type="checkbox"/>	Decreased <input type="checkbox"/>	Normal or increased <input type="checkbox"/>	not done <input type="checkbox"/>	unknown <input type="checkbox"/>
Pneumococcus	Absent <input type="checkbox"/>	Decreased <input type="checkbox"/>	Normal or increased <input type="checkbox"/>	not done <input type="checkbox"/>	unknown <input type="checkbox"/>

## **C- CLINICAL STATUS**

### **1- General manifestations**

General manifestations before this HSCT Yes ☐ No ☐ unknown ☐

If YES, specify: Malnutrition ☐ Protracted diarrhea ☐

Respiratory impairment ☐ If YES, was the patient ventilated ☐

Renal impairment ☐ Liver impairment ☐

Central Nervous System impairment ☐ Mental retardation ☐ Microcephaly ☐

Skin involvement ☐ Bone marrow failure ☐

Other ☐, if OTHER: specify.....

### **2- Neoplasia**

Neoplasia before this HSCT Yes ☐ No ☐ unknown ☐

If YES, specify:

B-cell lymphoproliferative disorder ☐ Leukemia ☐

MDS ☐ Lymphoma ☐ Solid tumour ☐

Other ☐

Therapy used:

Chemotherapy ☐ Radiotherapy ☐ Rituximab ☐

Other ☐, if OTHER: specify.....

Tolerance: Good ☐ Fair ☐ Poor ☐ unknown ☐

Outcome: Complete Remission ☐ Partial Remission ☐ No response ☐

unknown ☐

### 3- Infections

Did infection(s) occur before this HSCT?

Yes |\_\_| No |\_\_| unknown |\_\_|

If YES, specify type(s):

Location of infection	Type of micro-organism documented
<b>Septicemia</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Rotavirus <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Pulmonary</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> RSV <input type="checkbox"/> Para-influenzae <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> Pneumocystis jiroveci <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Meningeal</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Cutaneous</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism

<b>Liver</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> Cryptosporidia <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Bone and joints</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Gut</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Rotavirus <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> Pneumocystis jiroveci <input type="checkbox"/> Cryptosporidia <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Other location, specify:</b> .....	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Rotavirus <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> RSV <input type="checkbox"/> Para-influenzae <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> Pneumocystis jiroveci <input type="checkbox"/> Cryptosporidia <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism

#### 4- Patient's viral status

Patient's CMV status

Positive |\_\_\_|   Negative |\_\_\_|   not done |\_\_\_|   unknown |\_\_\_|

Patient's EBV status

Positive |\_\_\_|   Negative |\_\_\_|   not done |\_\_\_|   unknown |\_\_\_|

#### 5- Splenectomy

Did the patient have a splenectomy prior to HSCT?

Yes |\_\_\_|   No |\_\_\_|   unknown |\_\_\_|



## 6- **SCID only: pre-HSCT GvHD**

Clinical GvHD prior to HSCT	Yes <input type="checkbox"/>	No <input type="checkbox"/>	unknown <input type="checkbox"/>
If YES, specify:			
Did GvHD occur after blood transfusion?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	unknown <input type="checkbox"/>
Maternal T cell engraftment	Yes <input type="checkbox"/>	No <input type="checkbox"/>	unknown <input type="checkbox"/>
Number of maternal T cells ( $\times 10^9/L$ )	<input type="text"/>		
Test used:			
	HLA typing <input type="checkbox"/>	Microsatellite <input type="checkbox"/>	FISH <input type="checkbox"/>
Associated clinical manifestations	Yes <input type="checkbox"/>	No <input type="checkbox"/>	unknown <input type="checkbox"/>
If YES, specify:			
	Skin <input type="checkbox"/>	Liver <input type="checkbox"/>	Gut <input type="checkbox"/>
Treatment	Yes <input type="checkbox"/>	No <input type="checkbox"/>	unknown <input type="checkbox"/>

## 7- **Autoimmunity**

Autoimmune cytopenia	Yes <input type="checkbox"/>	No <input type="checkbox"/>	unknown <input type="checkbox"/>
If YES, specify:			
Autoimmune hemolytic anaemia (AIHA) <input type="checkbox"/>			
Autoimmune neutropenia <input type="checkbox"/>			
Immune Thrombocytopenic Purpura (ITP) <input type="checkbox"/>			
Other autoimmune features <input type="checkbox"/> ; If OTHER, specify:			
Colitis <input type="checkbox"/> Endocrinopathy <input type="checkbox"/> Arthritis <input type="checkbox"/> Autoimmune hepatitis <input type="checkbox"/>			
Other <input type="checkbox"/> ; if OTHER, specify: .....			
Did the patient receive a prolonged immunosuppressive therapy (>3 months)?			
Yes <input type="checkbox"/> No <input type="checkbox"/> unknown <input type="checkbox"/>			

## V - HAEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT)

Date of HSCT

|\_|\_|\_|\_| |\_|\_|\_|\_| |\_|\_|\_|\_|  
day month year

### **A- CONDITIONING OF RECIPIENT**

Chronological number of the graft

|\_|\_|

Patient's weight (kg)

|\_|\_|\_|\_|,|\_|\_|

Patient's height (cm)

|\_|\_|\_|\_|

Body area (m<sup>2</sup>) (*calculated*)

|\_|\_|,|\_|\_|\_|

**Conditioning**

Yes |\_|\_| No |\_|\_| unknown |\_|\_|

If YES, type of conditioning

Full intensity |\_|\_| Reduced intensity |\_|\_| unknown |\_|\_|

**Drugs and doses used**

Indicate the total dose in mg/kg or mg/m<sup>2</sup> over the total number of days

Busulfan |\_|\_|

Total dose (mg/kg) |\_|\_|\_|\_|,|\_|\_|

Route of administration

Oral |\_|\_| Intravenous |\_|\_| unknown |\_|\_|

Dose adaptation

|\_|\_|

Treosulfan |\_|\_|

Total dose (g/m<sup>2</sup>) |\_|\_|\_|\_|,|\_|\_|

Fludarabine |\_|\_|

Total dose (mg/m<sup>2</sup>) |\_|\_|\_|\_|,|\_|\_|

Cyclophosphamide |\_|\_|

Total dose (mg/kg) |\_|\_|\_|\_|,|\_|\_|

Melphalan |\_|\_|

Total dose (mg/m<sup>2</sup>) |\_|\_|\_|\_|,|\_|\_|

Thiotepa |\_|\_|

Total dose (mg/kg) |\_|\_|\_|\_|,|\_|\_|

ATG |\_|\_|

Total dose (mg/kg) |\_|\_|\_|\_|,|\_|\_|

Other, ..... |\_|\_|

Total dose (mg/kg) |\_|\_|\_|\_|,|\_|\_|

In-vivo monoclonal antibody:

Alemtuzumab |\_|\_|

Other in-vivo monoclonal antibody |\_|\_|, If OTHER, specify:.....

Total dose (mg/kg) |\_|\_|\_|\_|,|\_|\_|

**Radio immunotherapy**

Yes |\_|\_| No |\_|\_| unknown |\_|\_|

**Radiotherapy**

Yes |\_|\_| No |\_|\_| unknown |\_|\_|

If YES, specify site of radiation:.....

**TBI**

Yes |\_|\_| No |\_|\_| unknown |\_|\_|

Total dose (Gy) |\_|\_|\_|\_|,|\_|\_|

### **B- SOURCE OF STEM CELLS**

Source of stem cells

Bone Marrow |\_|\_| Peripheral blood |\_|\_|

Bone Marrow + Peripheral blood |\_|\_|

Cord blood |\_|\_|

Bone marrow + Cord Blood |\_|\_| Peripheral blood + Cord blood |\_|\_|

**T-cell depletion**

Yes ☐ No ☐ unknown ☐

If YES, specify modality:

Positive selection of CD34+ cells ☐ CD3/CD19 depletion ☐

Negative selection ☐, specify antibody.....

Other selection ☐, specify antibody..... unknown ☐

Number of viable nucleated cells infused ( $\times 10^8/\text{kg}$ )

Number of CD34 cells infused ( $\times 10^6/\text{kg}$ )

Number of CD3/T cells infused ( $\times 10^6/\text{kg}$ )

Route of administration of the graft Intra-venous ☐ Intra-medullary ☐ unknown ☐

**C- PROPHYLAXIS OF GVHD**

**Prophylaxis of GvHD**

Yes ☐ No ☐ unknown ☐

If YES, specify drug(s):

Methotrexate ☐ Duration (months)

Cyclosporin ☐ Duration (months)

Corticosteroids ☐ Duration (months)

Mycophenolate Mofetil (MMF) ☐ Duration (months)

Tacrolimus ☐ Duration (months)

Other ☐ Duration (months)

If OTHER, specify ..... Duration (months)

**D- PROPHYLAXIS OF INFECTIONS**

Precautions taken to reduce the role of infections None ☐

Trexler isolator ☐ Laminar air flow ☐ HEPA filtered room ☐

Other ☐ unknown ☐

Bacterial intestinal decontamination Yes ☐ No ☐ unknown ☐

Fungal intestinal decontamination Yes ☐ No ☐ unknown ☐

Prophylactic infusion of Immunoglobulins Yes ☐ No ☐ unknown ☐

Prophylactic use of trimethoprim-sulfamethoxazole Yes ☐ No ☐ unknown ☐

Viral prophylaxis Yes ☐ No ☐ unknown ☐

If YES, specify drug: Acyclovir Yes ☐ No ☐ unknown ☐

Other drug: Yes ☐ No ☐, If OTHER, specify: ..... unknown ☐

Fungal prophylaxis Yes ☐ No ☐ unknown ☐

**E- OTHER PROPHYLAXIS**

Veno-Occlusive Disease (VOD) prophylaxis Yes ☐ No ☐ unknown ☐

If YES, did the patient receive Defibrotide ? Yes ☐ No ☐ unknown ☐

## F- DONOR

Age at time of HSCT (years) (not applicable for Cord Blood)

Donor sex Male  Female

Donor relationship Sibling  Parent  Other related

Unrelated  If UNRELATED, specify (donor registry and number): .....

Donor's CMV status Positive  Negative  unknown

Donor's EBV status Positive  Negative  unknown

### Recipient/donor degree of compatibility

**i** Indicate the number of mismatches per locus. If NOT DONE, write "nd" in the box

		Number of mismatches	
		Serologic	Allelic
Class I	A	<input type="text"/>	<input type="text"/>
	B	<input type="text"/>	<input type="text"/>
	C	<input type="text"/>	<input type="text"/>
Class II	DRB1	<input type="text"/>	<input type="text"/>
	DQB1	<input type="text"/>	<input type="text"/>
	DPB1	<input type="text"/>	<input type="text"/>

### Compatibility recipient/donor

Compatible

Incompatible 0,5AG  Incompatible 1AG  Incompatible 1,5AG

Incompatible 2AG  Incompatible 2,5AG  Incompatible 3AG  Incompatible 3,5AG

Incompatible 4AG  Incompatible 4,5AG  Incompatible 5AG  Incompatible 5,5AG

unknown

Number of loci studied: 6  8  10  12  unknown

Please upload the HLA typing forms of both patient and donor in the dedicated section

If Peripheral blood, drug used for peripheral blood mobilisation:

G-CSF  AMD3100  Plerixafor  Other , if OTHER, specify .....

## VI - RESULTS OF HSCT AT 6 MONTHS

**i** Disease status should be assessed at 6 months post HSCT.

Please give values from the same time point.

If death or subsequent HSCT before 6 months, please give the latest date of disease assessment before death/next HSCT.

Date of disease assessment after HSCT

|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
day month year

### A- EVIDENCE FOR ENGRAFTMENT/CHIMAERISM

Time interval between HSCT and overall engraftment (weeks)

|\_|\_|\_|

T-cells engraftment

Full donor |\_|\_| Predominantly donor |\_|\_|

Predominantly recipient |\_|\_| Full recipient |\_|\_| not done |\_|\_| unknown |\_|\_|

If FISH analysis was done, specify value (%)

|\_|\_|\_|\_|\_|

Granulocytes engraftment

Full donor |\_|\_| Predominantly donor |\_|\_|

Predominantly recipient |\_|\_| Full recipient |\_|\_| not done |\_|\_| unknown |\_|\_|

If FISH analysis was done, specify value (%)

|\_|\_|\_|\_|\_|

Platelets engraftment

Present |\_|\_| Absent |\_|\_| not done |\_|\_| unknown |\_|\_|

Overall engraftment at 6 months post HSCT is considered

Complete |\_|\_| Partial |\_|\_| Absent |\_|\_| not done |\_|\_| unknown |\_|\_|

If FISH analysis was done, specify value (%)

|\_|\_|\_|\_|\_|

If graft failure, specify:

Primary graft failure |\_|\_| Secondary graft failure |\_|\_|

Assessment date of graft failure

|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
day month year

Outcome

Death |\_|\_| Next HSCT |\_|\_| Alive with original disease |\_|\_|

### B- HAEMATOLOGICAL RECONSTITUTION

Granulocytes >  $0.5 \times 10^9/l$

Yes |\_|\_| No |\_|\_| Not applicable |\_|\_| unknown |\_|\_|

If YES, date granulocytes >  $0.5 \times 10^9/l$

|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
day month year

Platelets >  $20 \times 10^9/l$

Yes |\_|\_| No |\_|\_| Not applicable |\_|\_| unknown |\_|\_|

If YES, date platelets >  $20 \times 10^9/l$

|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
day month year

Platelets >  $50 \times 10^9/l$

Yes |\_|\_| No |\_|\_| Not applicable |\_|\_| unknown |\_|\_|

If YES, date platelets >  $50 \times 10^9/l$

|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
day month year

Hemoglobin > 10 g/dl

Yes |\_|\_| No |\_|\_| Never below |\_|\_| unknown |\_|\_|

Cytokines used

Yes |\_|\_| No |\_|\_| unknown |\_|\_|

**i** Not applicable = never below



## D- INFECTIONS

Did infection(s) occur **after** HSCT?

Yes ☐ No ☐ unknown ☐

If YES, specify type(s):

Location of infection	Type of micro-organism documented
<b>Septicemia</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Rotavirus <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify: ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Pulmonary</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> RSV <input type="checkbox"/> Para-influenzae <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify: ..... <input type="checkbox"/> Pneumocystis jiroveci <input type="checkbox"/> New emerging infectious agent, specify: ..... <input type="checkbox"/> Non conventional agent, specify: ..... <input type="checkbox"/> Other micro-organism, specify : ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Meningeal</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify:: ..... <input type="checkbox"/> New emerging infectious agent, specify : ..... <input type="checkbox"/> Non conventional agent, specify : ..... <input type="checkbox"/> Other micro-organism, specify : ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Cutaneous</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Rotavirus <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify:: ..... <input type="checkbox"/> New emerging infectious agent, specify : ..... <input type="checkbox"/> Non conventional agent, specify : ..... <input type="checkbox"/> Other micro-organism, specify : ..... <input type="checkbox"/> unknown or not documented micro-organism

<b>Liver</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify:: ..... <input type="checkbox"/> Cryptosporidia <input type="checkbox"/> New emerging infectious agent, specify : ..... <input type="checkbox"/> Non conventional agent, specify : ..... <input type="checkbox"/> Other micro-organism, specify : ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Bone and joints</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify:: ..... <input type="checkbox"/> New emerging infectious agent, specify : ..... <input type="checkbox"/> Non conventional agent, specify : ..... <input type="checkbox"/> Other micro-organism, specify : ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Gut</b>	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Rotavirus <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify:: ..... <input type="checkbox"/> Pneumocystis jiroveci <input type="checkbox"/> Cryptosporidia <input type="checkbox"/> New emerging infectious agent, specify : ..... <input type="checkbox"/> Non conventional agent, specify : ..... <input type="checkbox"/> Other micro-organism, specify : ..... <input type="checkbox"/> unknown or not documented micro-organism
<b>Other location, specify:</b> .....	<input type="checkbox"/> Bacteria <input type="checkbox"/> Mycobacteria <input type="checkbox"/> BCG Virus: <input type="checkbox"/> EBV <input type="checkbox"/> ADV <input type="checkbox"/> CMV <input type="checkbox"/> HSV <input type="checkbox"/> VZV <input type="checkbox"/> Rotavirus <input type="checkbox"/> Norovirus <input type="checkbox"/> Enterovirus <input type="checkbox"/> RSV <input type="checkbox"/> Para-influenzae <input type="checkbox"/> Other virus, specify: ..... Fungi: <input type="checkbox"/> Candida sp. <input type="checkbox"/> Aspergillosis sp. <input type="checkbox"/> Other fungi, specify:: ..... <input type="checkbox"/> Pneumocystis jiroveci <input type="checkbox"/> Cryptosporidia <input type="checkbox"/> New emerging infectious agent, specify : ..... <input type="checkbox"/> Non conventional agent, specify : ..... <input type="checkbox"/> Other micro-organism, specify : ..... <input type="checkbox"/> unknown or not documented micro-organism



## **E- GvHD after HSCT**

Did **acute GvHD (aGvHD)** occur after HSCT?

Yes ☐ No ☐ unknown ☐

If YES, specify:

**Organ(s) involved**

Skin ☐ Liver ☐ Gut ☐ CNS ☐ Eyes ☐ Lungs ☐ Mouth ☐

Other ☐, if OTHER, specify: ..... unknown ☐

**Maximum grade** Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ unknown ☐

**Date of aGvHD onset**        
day month year

**Drug(s) used for treatment**

Corticosteroids ☐ Cyclosporine ☐ Mycophenolate Mofetil (MMF) ☐

Tacrolimus ☐ Sirolimus ☐ ATG ☐ Alemtuzumab ☐ Anti rIL2 ☐

Extra-corporeal Photopheresis (ECP) ☐ other ☐ If OTHER, specify: .....

**Outcome of aGvHD** Resolution ☐ Recurrence ☐ Persistence ☐ unknown ☐

**Duration of aGvHD (days)**

Did **chronic GVHD (cGvHD)** occur after HSCT?

Yes ☐ No ☐ unknown ☐

**Date of cGvHD onset**        
day month year

If YES, specify:

**Organ(s) involved**

Skin ☐ Liver ☐ Gut ☐ Mouth ☐ Lungs ☐ Eyes ☐ Sclerodermy ☐

CNS ☐ Other ☐, if OTHER, specify: ..... unknown ☐

**Intensity** Limited ☐ Extensive ☐ unknown ☐

**Drug(s) used for treatment**

Corticosteroids ☐ Cyclosporine ☐ Mycophenolate Mofetil (MMF) ☐

Tacrolimus ☐ Sirolimus ☐ ATG ☐ Alemtuzumab ☐ Tyrosine Kinase inhibitors ☐

Anti rIL2 ☐ Thalidomide ☐ Locally administered Immunosuppressive agents only ☐

Extra-corporeal Photopheresis (ECP) ☐ Other ☐, If OTHER, specify: .....

**Outcome of cGvHD** Resolution ☐ Recurrence ☐ Persistence ☐ unknown ☐

**Duration of cGvHD (months)**

## **F- POST-TRANSPLANT B-CELL LYMPHOPROLIFERATIVE DISORDER (B-PTLD)**

Did B-PTLD occur after HSCT?

Yes ☐ No ☐ unknown ☐

If YES, specify:

Interval between HSCT and B-PTLD occurrence (weeks)

E.B.V Yes ☐ No ☐ unknown ☐

Donor origin Yes ☐ No ☐ unknown ☐

**Outcome of B-PTLD** Complete remission ☐ Partial remission ☐ Death ☐

## **G- OTHER COMPLICATIONS**

Did other complications occur after HSCT?

Yes ☐ No ☐ unknown ☐

If YES, specify:

Hepatic Veno-Occlusive Disease ☐ Pulmonary Hypertension ☐

Chronic liver disease ☐ Chronic pulmonary disease ☐

Nutritional deficiency ☐ Micro-angiopathy ☐ Haemorrhagic cystitis ☐

Other complications ☐, If OTHER, specify: .....

## **H- AUTOIMMUNE COMPLICATIONS**

Did autoimmune cytopenia occur after HSCT?

Yes ☐ No ☐ unknown ☐

If YES, specify:

Autoimmune hemolytic anaemia (AIHA) ☐ Immune Thrombocytopenic Purpura (ITP) ☐

Autoimmune neutropenia ☐

Other autoimmune features ☐, if YES, specify:

Colitis ☐ Endocrinopathy ☐ Arthritis ☐ Autoimmune hepatitis ☐

Other ☐, if OTHER, specify: .....

Did the patient receive a prolonged immunosuppressive therapy (>3 months)?

Yes ☐ No ☐ unknown ☐

## **I- DISEASE STATUS**

Status of primary disease at 6 months post HSCT is:

Cured ☐ Improved ☐ Unchanged ☐ Worse ☐ Not applicable ☐ unknown ☐

① **Cured:** no need for any supportive therapy

① **Improved:** need for supportive therapy directly linked to the primary disease (eg: Ig replacement therapy for a SCID patient which is to be differentiated from a patient who is under antibioprophylaxis for a splenectomy that was done anytime for his primary disease)

① **Not applicable:** death before assessment

## VII - CELL THERAPY AFTER HSCT

If additional cell therapy was given after HSCT, specify type(s):

### CD34 top-up/boost

Number of CD34 top-up infusions

Date of CD34 top-up infusions

			_ _
			_
_ _	_ _	_ _ _ _	_
day	month	year	
_ _	_ _	_ _ _ _	_
day	month	year	
_ _	_ _	_ _ _ _	_
day	month	year	

### Donor Lymphocytes Infusion (DLI)

Date of first DLI infusion

Total number of DLI infusions

			_
_ _	_ _	_ _ _ _	_
day	month	year	
			_

### Cytotoxic T Lymphocytes (CTL)

Date of first CTL infusion

Total number of CTL infusions

			_
_ _	_ _	_ _ _ _	_
day	month	year	
			_

### Mesenchymal Stem Cells (MSC)

Date of first MSC infusion

Total number of MSC infusions

			_
_ _	_ _	_ _ _ _	_
day	month	year	
			_

### Other cells administered

If YES, specify type : .....

Date of first infusion

Total number of infusions

_ _	_ _	_ _ _ _	_
day	month	year	
			_

If YES, specify type : .....

Date of first infusion

Total number of infusions

_ _	_ _	_ _ _ _	_
day	month	year	
			_

If YES, specify type : .....

Date of first infusion

Total number of infusions

_ _	_ _	_ _ _ _	_
day	month	year	
			_

| | | | | | | | | |  
 day month year

Infection ☐ Pneumonitis ☐ GvHD ☐ Drug toxicity ☐ Haemorrhage ☐  
Veno-Occlusive Disease (VOD) ☐ Multiple Organ Failure ☐ Graft rejection ☐  
B cell lymphoproliferative syndrome ☐ unknown ☐  
Other ☐ if OTHER, specify:.....

## IX - COMMENTS

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