Stem CEll Transplant
for primary Immune Deficiencies in Europe

FOLLOW UP REPORT

One year after HSCT and annually thereafter

Chairman
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& EBMT-IEWP
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FOLLOW-UP 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 - INVESTIGATOR INFORMATION

Centre Identification Number |___|___|___|___|

Name of the Institution .....

Referring physician .....

Address .....

.....

.....

.....

Phone number .....

Fax number .....

E-mail .....

Data manager .....

Phone number .....

E-mail .....

II - RECIPIENT INFORMATION

Family name (*initial*) |___|

First name (*initial*) |___|

Sex Male |___| Female |___|

Date of Birth |_ _|_ _| |_ _|_ _| |_ _|_ _|_ _|_ _|
day *month* *year*

Date of last HSCT |_ _|_ _| |_ _|_ _| |_ _|_ _|_ _|_ _|
day *month* *year*

Date of follow up |_ _|_ _| |_ _|_ _| |_ _|_ _|_ _|_ _|
day *month* *year*

ⓘ *(date of last follow up or latest date of disease assessment if the patient has died since the last report)*

III - RESULT OF HSCT

A) Reconstitution

Was graft rejected? Yes |___| No |___| unknown |___|

If YES, specify:

Date of first assessment |_ _|_ _| |_ _|_ _| |_ _|_ _|_ _|_ _|
day *month* *year*

Autologous reconstitution Partial |_ _| Complete |_ _| unknown |_ _|

If NO, specify:

Haematopoietic chimaerism Complete |___| Partial |___| Absent |___| unknown |___|

If FISH analysis was done, specify value (%) |___|___|___|

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 (%) |___|___|___|

Immunological reconstitution

T cells (CD3) Absent |___| Low |___| Normal or high |___| not done |___|

Value (10.9/L) |___|___|.|___|___|___|

B cells (CD19) Absent |___| Low |___| Normal or high |___| not done |___|

Value (10.9/L) |_ _|_ _|.|_ _|_ _|_ _|

Does the patient receive Ig replacement therapy? Yes |___| No |___| unknown |___|

Does the patient receive antibiotics prophylaxis? Yes |___| No |___| unknown |___|

Does the patient receive antifungal prophylaxis? Yes |___| No |___| unknown |___|

B) GvHD

In patient with acute GvHD previously reported, is it still present?

Yes |___| No |___| Not appl. |___| unknown |___|

In patient with chronic GvHD previously reported, is it still present?

Yes |___| No |___| Not appl. |___| unknown |___|

In patient with no cGvHD previously reported, has chronic GvHD occured since last report?

Yes |___| No |___| unknown |___|

If YES to any of the three questions above:

Organ(s) involved

Skin |___| Liver |___| Gut |___| Mouth |___| Lungs |___| Eyes |___| Sclerodermy |___|
CNS |___| Other |___|, if OTHER, specify: …….. unknown |___|

Intensity Limited |_ _| Extensive |_ _| unknown |_ _|

Duration of GvHD treatment more than 12 months Yes |___| No |___| unknown |___|

C) Infections

Have infection(s) occured **since** last report? Yes |___| No |___| unknown |___|

If YES, specify types(s):

Location of infection	Type of micro-organism documented
Septicemia	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ EBV ☐ ADV ☐ CMV ☐ HSV ☐ VZV ☐ Rotavirus ☐ Norovirus ☐ Enterovirus ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ New emerging infectious agent, specify: …… ☐ Non conventional agent, specify: …… ☐ Other micro-organism, specify: …… ☐ Unknown or not documented micro-organism
Pulmonary	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ EBV ☐ ADV ☐ CMV ☐ HSV ☐ VZV ☐ RSV ☐ Para-influenzae ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ Pneumocystis jiroveci ☐ New emerging infectious agent, specify: …… ☐ Non conventional agent, specify: …… ☐ Other micro-organism, specify: …… ☐ Unknown or not documented micro-organism
Meningeal	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ EBV ☐ ADV ☐ CMV ☐ HSV ☐ VZV ☐ Norovirus ☐ Enterovirus ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ New emerging infectious agent, specify: …… ☐ Non conventional agent, specify: …… ☐ Other micro-organism, specify: …… ☐ Unknown or not documented micro-organism
Cutaneous	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ CMV ☐ HSV ☐ VZV ☐ Norovirus ☐ Enterovirus ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ New emerging infectious agent, specify: …… ☐ Non conventional agent, specify: …… ☐ Other micro-organism, specify: …… ☐ Unknown or not documented micro-organism

Liver	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ EBV ☐ ADV ☐ CMV ☐ HSV ☐ VZV ☐ Norovirus ☐ Enterovirus ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ Cryptosporidia ☐ New emerging infectious agent, specify: …….. ☐ Non conventional agent, specify: …….. ☐ Other micro-organism, specify: …….. ☐ Unknown or not documented micro-organism
Bone and joints	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ EBV ☐ ADV ☐ CMV ☐ HSV ☐ VZV ☐ Enterovirus ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ New emerging infectious agent, specify: …….. ☐ Non conventional agent, specify: …….. ☐ Other micro-organism, specify: …….. ☐ Unknown or not documented micro-organism
Gut	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ EBV ☐ ADV ☐ CMV ☐ HSV ☐ VZV ☐ Rotavirus ☐ Norovirus ☐ Enterovirus ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ Pneumocystis jiroveci ☐ Cryptosporidia ☐ New emerging infectious agent, specify: …….. ☐ Non conventional agent, specify: …….. ☐ Other micro-organism, specify: …….. ☐ Unknown or not documented micro-organism
Other location, specify: ……	☐ Bacteria ☐ Mycobacteria ☐ BCG Virus: ☐ EBV ☐ ADV ☐ CMV ☐ HSV ☐ VZV ☐ Rotavirus ☐ Norovirus ☐ Enterovirus ☐ RSV ☐ Para-influenzae ☐ Other virus, specify: …… Fungi: ☐ Candida sp. ☐ Aspergillosis sp. ☐ Other fungi, specify: …… ☐ Pneumocystis jiroveci ☐ Cryptosporidia ☐ New emerging infectious agent, specify: …….. ☐ Non conventional agent, specify: …….. ☐ Other micro-organism, specify: …….. ☐ Unknown or not documented micro-organism

D) Complications

Have significant complications occured since last report? Yes |___| No |___| unknown |___|

If YES, specify:

Pulmonary hypertension |___| Chronic pulmonary disease |___| Chronic liver disease |___|

Osteopenia/osteoporosis |___| Growth retardation |___|

Nutritional deficiency |___| If YES; nutritional support required |___|

Endocrine pathology |___| Abnormal puberty |___| Infertility |___|

Neurocognitive impairment |___| Motor disability |___|

Psychological difficulties |___| Difficulties at school |___| Socioprofessional difficulties |___|

Other complications |___| If YES, specify: ……..

Has autoimmune disease occured since last report? Yes |___| No |___| unknown |___|

If YES, specify: ……..

Has neoplasia occured since last report? Yes |___| No |___| unknown |___|

If YES, specify:

Hodgkin's disease |___| Non-Hodgkin lymphoma |___| Acute leukaemia |___| MDS |___|
Chronic leukaemia |___| Solid tumour |___|, specify: ……..

Other neoplasia |___|, specify: ……..

If available, International Classification of Diseases (ICD10) code: |_____|

Date of diagnosis |_ _|_ _| |_ _|_ _| |_ _|_ _|_ _|_ _|
month *day* *year*

E) Survival status

Is the patient alive? Yes |___| *No |___| Lost to follow up |___| unknown |___|

** Please report the cause of death on page 9*

Status of primary disease at this follow up is:

Cured |___| Improved |___| Unchanged |___| Worse |___| unknown |___|

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

ⓘ **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)*

IV – CELL THERAPY

If additional cell therapy was given since last report, 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 |___|___| |___|___| |___|___|___|___|
day *month* *year*

Total number of DLI infusions |___|

Cytotoxic T Lymphocytes (CTL) |___|

Date of first CTL infusion |___|___| |___|___| |___|___|___|___|
day *month* *year*

Total number of CTL infusions |___|

Mesenchymal Stem Cells (MSC) |___|

Date of first MSC infusion |___|___| |___|___| |___|___|___|___|
day *month* *year*

Total number of MSC infusions |___|

Other cells administered |___|

If yes, type : ……..……..

Date of first infusion |___|___| |___|___| |___|___|___|___|
day *month* *year*

If yes, type : ……..……..

Date of first infusion |___|___| |___|___| |___|___|___|___|

If yes, type : ……..……..

Date of first infusion |___|___| |___|___| |___|___|___|___|

VI - DEATH

Date of death |___|___| |___|___| |___|___|___|___|
day *month* *year*

Primary cause of death:

Infection |___| Pneumonitis |___| GvHD |___| Drug toxicity |___| Haemorrhage |___|

Veno-Occlusive Disease (VOD) |___| Multiple Organ Failure |___| Graft rejection |_ _|

B cell lymphoproliferative syndrome |_ _| Unknown |___|

Other |___| specify:……

Secondary cause(s) of death:

Infection |___| Pneumonitis |___| GvHD |___| Drug toxicity |___| Haemorrhage |___|

Veno-Occlusive Disease (VOD) |___| Multiple Organ Failure |___| Graft rejection |_ _|

B cell lymphoproliferative syndrome |_ _| Unknown |___|

Other |___| specify:……

VII - COMMENTS

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