EBMT Registry

Donor outcome short-term

Guide to the completion of the EBMT data collection form: Donor_Short_Term_Outcome_v1.1

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EBMT Registry

EBMT Clinical Research & Registry Department

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Donation procedure and up to 30 days after

Each donation procedure must have its own report.

Submit one form if:

- There is only one donation of bone marrow (BM) stem cells; or

- There is only one donation of peripheral blood (PB) stem cells; or

- There is only one donation of Donor lymphocytes (DLI); or

- There is a donation of PB stem cells, followed by a donation of BM stem cells, within the period of a week.

Submit two forms if:

- There is a donation of BM, followed by a donation of PB. Each of these donations should have its own form.

- The interval between two donations is more than a week

In the new EBMT Registry system used by the EBMT, both related and unrelated donor outcome data is registered in the same way and is not linked to the patient (recipient) record directly. This has to do with data protection of the donor data and the consent provided by the donor.

Note: In addition to the Donor outcome reports covered in Donor registration, short-term and long-term follow up, some minimal information on donors is also collected within the patient (recipient) records. Fields and questions related to donors in the Patient registry are not considered as donor outcome reporting. Instructions on these fields are provided in the allogeneic HCT form.

Important: When this report is to be entered into EBMT Registry, the event date should be the Collection date.

Donor data

Donor weight at collection

Provide the weight of the donor (in kilograms) at collection. If the weight was not evaluated, select **Not evaluated**. If the weight is unknown, select **Unknown.**

Relationship to recipient

Indicate if the donor and recipient are related or not.

If the recipient and the donor have no family connection, select **Unrelated donor**. If the recipient and the donor are related, select **Related donor** and specify in the checkbox the compatibility between the donor and recipient:

- **HLA identical sibling**: if the recipient and their donor have the same parents (but are not identical twins) and the HLA antigens are identical, it is most likely that both siblings are therefore 'genotypically' identical, i.e. both siblings have the same genes for the HLA antigens. This is an HLA-identical sibling transplant.
- **Syngeneic**: if the transplant is from a monozygotic twin, known as "identical twins" the transplant is defined as syngeneic and the histocompatibility genes in donor and recipient are the same.
- **HLA-matched other relative**: occasionally other family members (parents, cousins, half siblings, etc.) could be HLA-identical to the recipient but could not have inherited the same copies of chromosome 6 as the recipient (because they don't share the same parents). This is defined as an HLA matched other family member.
- **HLA-mismatched relative**.

Relationship to recipient

If answered HLA-matched other relative or HLA-mismatched relative in the previous question, specify the degree of the relationship between the donor and recipient:

- **First degree**: the recipients parents, siblings, and/or children;
- **Second degree**: the recipients grandparents, grandchildren, uncles, aunts, nephews, nieces and/or half-siblings;
- **Third degree**: the recipients great-grandparents, great grandchildren, great uncles/aunts, and/or first cousins;
- **Fourth degree**: recipients' great-great-grandparents, great-great-grandchildren, and/or first cousins once-removed (i.e. the children of the individual's first cousins).

Transplant centre and recipient identification

EBMT Centre Identification Code (CIC)

Provide the CIC number of the centre that performed the transplant. The EBMT will provide a Centre Identification Code (CIC) to collection centres or donor registries if they do not have a membership CIC. If you do not know the CIC of the centre or donor registry where the collection was performed, please contact the EBMT Registry at registryhelpdesk@ebmt.org.

EBMT Centre name

Report the name of the centre that performed the transplant.

EBMT Unique Identification Code (UIC)

Report the patient number (recipient) in the EBMT database. This field should be completed only if:

- The donor was related to recipient (patient), or
- The donor was unrelated but the donation took place in the country of treatment.

Patient ID

Report the recipient (patient) ID number. This field is mandatory if the donor and recipient are unrelated.

Hospital Unique Patient Number or code (UPN)

Report the UPN number of the recipient (patient). This field should be completed only if:

- The donor was related to the recipient (patient), or
- The donor was unrelated but the donation took place in the country of treatment.

Initials

Fill in the first letter of the recipient's first name and the first letter of their family name (surname). This field is mandatory for submission.

Date of birth

Provide the date the recipient was born. This field is mandatory for submission.

Date of treatment (HCT/CT)

Report the date of allogeneic treatment (HCT/CT/other) took place. (Only if product has been infused and the date is available to the collection centre.)

Collection centre identification

EBMT Centre Identification Code (CIC)

Report, if known, the CIC number of the collection centre or donor registry.

Collection centre

Report the full name of the collection centre, including city and country.

Donor registry

Only for unrelated donors, report the full name of the donor registry that collected material. If available, add also the BMDW/WMDA code which can be found at: https://statistics.wmda.info/

Contact person

Report the name of the person who can be contacted for further questions about the collection.

Product

Donated product:

Select the checkbox to specify which product was donated to the recipient:

- **BM** (including collection of MSC): Bone marrow cells, including mesenchymal cells.
- **PBSC**: peripheral blood collection by peripheral or central line techniques.
- **Both, BM and PBSC**: collection of bone marrow followed by peripheral blood of the same donor within the same defined collection procedure (E.g. because of insufficiency of first chosen source or other circumstances, peripheral blood stem cells as well as bone marrow were collected).
- **Unstimulated leukapheresis** (e.g. lymphocytes (DLI), etc.)

If the product is not listed, select **Other** and specify what was donated.

Donor evaluation before donation

Date of evaluation

Report the date of donor evaluation before the donation took place. If the date is unknown, select **Unknown.**

Co-existing disease or organ impairment present at time of evaluation/donation

Answer **No**, If there was no co-existing disease or organ impairment present at time of evaluation/donation. If it is unknown, select **Unknown**.

If there was any co-existing disease or organ impairment present at time of evaluation/donation, select **Yes** and specify all diseases or organ impairment that were present by choosing the corresponding checkbox and indicating ICD code next to each of them. The ICD codes can be found on the WHO ICD website.

Select all that apply:

- **Cardiovascular**
- **Pulmonary**
- **Gastrointestinal**
- **Genito-urinary**
- **Neurological**
- **Immune/autoimmune**
- **Infectious**
- **Haematological**
- **Oncological**
- **Psychological**

If there was a co-existing disease or organ impairment which is not listed in above, select **Other** and specify the disease/impairment in the text field. Report the ICD code.

ICD version used

Report the ICD version which was used for this reporting.

Donation procedure

Collection date

Report the date when collection took place.

Chronological number of this donation procedure

Report the chronological number of this donation for the donor. It refers to the number of the donation procedure that this donor has undergone throughout his/her lifetime, including previous donations in other centres and/or for other recipients.

If > 1

The following questions are only applicable If the donor has donated before, thus if this donation is not the first one.

Same recipient

If this donor donated previously to the same recipient as reported in the current form, select Yes. If the donor donated previously to the other recipient, select **No**.

Centre of previous donation

Report the CIC and the name of the centre/donor registry where the previous collection for this donor took place. If it is unknown, select **Unknown**.

Date of previous donation

Report the date the previous collection for this donor took place. If it is unknown, select **Unknown**.

Was this product collection completed?

If the product collection reported with this form was completed, select **Yes**. If the product collection was not completed, select **No**.

Were haematopoietic growth factors used (e.g. G-CSF)?

Granulocyte colony-stimulating factors (G-CSF) are used to mobilise haematopoietic stem cells to the peripheral blood (e.g.: Filgrastim, Lenograstim, Pegfilgrastim, other).

If haematopoietic growth factors have not been used, select **No**.

If haematopoietic growth factors were used, select **Yes** and answer the following subquestions.

Product and brand name

Specify the product and brand name of the haematopoietic growth factors that were used selecting one of the following options:

- **G-CSF**
- **GM-CSF**
- **IL-2**
- **Euprotin**

If other type of haematopoietic growth factor was used select Other and specify in the text field.

G-CSF

If G-CSF was used, specify the type by selecting from the following list of options. Select the general option if the brand name of the injected product is not known, otherwise select the used brand name.

- **Filgrastim, not otherwise specified**
- **Neupogen**
- **Nivestim**
- **Ratiograstim**
- **Tevagastrim**
- **Zarzio**
- **Lenograstim, not otherwise specified**
- **Granocyte**
- **Myelostim**
- **Pegfilgrastim, not otherwise specified**
- **Neulasta**
- **Neulastim**
- **Neupopeg**

Total dose per injection (µg/kg)

Report the total dose per injection in micrograms per kilogram. If it is unknown, select **Unknown**.

Number of doses per day

Report the number of doses per day that were injected. If it is unknown, select **Unknown**.

Total number of doses

Report the total number of doses that were injected. If it is unknown, select **Unknown**.

Date of first injection

Report the date the first injection took place. If it is unknown, select **Unknown**.

Were cell binding inhibitors used (e.g. Plerixafor)?

If cell binding inhibitors were not used, select **No**. If cell binding inhibitors were used, select **Yes** and specify which cell binding inhibitors were used in the textfield and the date of the first injection. If it is unknown, select **Unknown**.

Was erythropoietin used?

If erythropoietin was not used, select **No**. If erythropoietin was used, select **Yes** and specify the erythropoietin in the text field. Report also the date of the first injection. If it is unknown, select **Unknown**.

Were other drugs used for mobilisation?

If there were no other drugs used for mobilisation, select **No**. If there were other drugs used for mobilisation, select **Yes** and specify the drugs used in the textfield, report also the date of the first injection. If it is unknown, select **Unknown**.

Apheresis collection

Number of apheresis performed

Report the number of aphereses that have been performed.

Collection technique

Select the checkbox to indicate which collection technique was used for the apheresis. Mark as **Unknown** if it is not known.

- **By peripheral veins;**
- **By central venous catheter.**

Bone Marrow collection

Anaesthesia

Report type of anaesthesia used for the bone marrow collection by selecting from the following answer options. Mark as **Unknown** if it is not known.

- **General;**
- **Epidural/spinal;**
- **Local.**

Autologous blood donation prior to collection?

Answer **Yes** if an autologous blood donation took place prior to collection. If there was no autologous blood donation, select **No**. Mark as **Unknown** if it is not known.

Was autologous blood re-transfused?

Answer **No**, If autologous blood was not re-transfused. If autologous blood was re-transfused, select **Yes**. Mark as **Unknown** if it is not known.

Complications in temporal association with the donation procedure

In this section, report any serious adverse event occurring within the interval between start of the donation procedure and day 30 after the end of donation procedure with ICD Coding. Serious adverse events (SAE) or serious adverse reactions (SAR) taking place after this date should be reported with **the Long-term Follow-up report**.

Death, whether it happened before or after 30 days from donation, should be reported by submitting **a Long term follow up report** in addition to this report.

IMPORTANT NOTE

Only report events with WHO toxicity grade 3 and 4, or SAEs that:

1. Lead to death
2. Are life-threatening events requiring in-patient hospitalisation or prolongation of existing hospitalisation due to WHO grade 3 or 4 toxicity or causing to
3. Lead to persistent or significant disability/incapacity

Serious adverse events observed

If there were no serious adverse events observed, select **No**. If there were serious adverse events observed, select **Yes** and specify details of each adverse event in sub-questions. If it is not known if there were any serious adverse events observed, select **Unknown**.

ICD code

Select the ICD code of the adverse event from a dropdown list. If the matching code can not be found select Other and specify the ICD code in the text field.

Other ICD code

The ICD codes can be found on the WHO ICD website.

Specify

Specify details of the adverse event.

Onset date

Report the onset date that the adverse event was observed. If the date is not known, mark as **Unknown**.

ICD version used

Report which ICD version was used for this reporting.

IMPORTANT NOTE

Unrelated donors: WMDA SEAR reporting

Reporting to WMDA is **mandatory for WMDA accredited registries** and highly recommended for all other registries.

Please go to WMDA website: https://wmda.info/

· Click on the left side: S(P)EAR Committee How to report S(P)EAR to the WMDA for information · Follow the link to the online reporting system:

http://www.surveygizmo.com/s3/720793/SEAR-and-SPEAR-2012

Donor behaviour

Would the donor donate again?

Based on the donor questionnaire or answer, report here donor experience and behaviour.

If the donor would not donate again in the future, select **No** and specify the reason why the donor would not donate again in the text field in English. If the donor would donate again, select **Yes**.If it is not known whether or not the donor would donate again, select **Unknown**.