Donor short-term outcome

Guide to the completion of the EBMT data collection form:
Donor_Short_Term_Outcome_v1.0

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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 (see question 18).

1. **Donor weight at collection:**

   Provide the weight of the donor (in kilograms) at collection.

2. **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**.

### 2.1. 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

#### 3. 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.

#### 4. EBMT Centre name:

Report the name of the centre that performed the transplant.
5. 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.

6. Patient ID:

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

7. 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.

8. 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.

9. Date of birth:

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

10. Date of treatment (HCT/CT):

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

Collection centre identification

11. EBMT Centre Identification Code (CIC):

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

12. Collection centre:

Report the full name of the collection centre, including city and country.
13. 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/

14. Contact person:

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

Product

15. 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

16. Date of evaluation:

Report the date of donor evaluation before the donation took place.

17. 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.

17.1. ICD version used:

Report the ICD version which was used for this reporting.

Donation procedure

18. Collection date:

Report the date when collection took place.

19. 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.

19.1. If > 1:

The following questions are only applicable if the donor has donated before, thus if this donation is not the first one.
19.1.1. 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.

19.1.2. Centre of previous donation:
Report the CIC and the name of the centre/donor registry where the previous collection for this donor took place.

19.1.3. Date of previous donation:
Report the date the previous collection for this donor took place.

20. 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.

21. 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.

21.1. Product and brand name:
Specify the product and brand name of the haematopoietic growth factors that were used in the textfield. You can find a list of known brand names in the Appendix.

21.2. Total dose per injection (µg/kg):
Report the total dose per injection in micrograms per kilogram.

21.3. Number of doses per day:
Report the number of doses per day that were injected.

21.4. Total number of doses:
Report the total number of doses that were injected.

21.5. Date of first injection:
Report the date the first injection took place.
22. 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.

23. 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.

24. 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.

25. Apheresis collection:

25.1. Number of apheresis performed:

Report the number of aphereses that have been performed.

25.2. Collection technique:

Select the checkbox to indicate which collection technique was used for the apheresis:

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

26. Bone Marrow collection:

26.1. Anaesthesia:

Report type of anaesthesia used for the bone marrow collection by selecting from the following answer options:

- **General**;
26.2. 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**.

26.3. Was autologous blood re-transfused?

Answer **No**, if autologous blood was not re-transfused. If autologous blood was re-transfused, select **Yes**.

**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

27. **Serious adverse events observed**:

If there were no serious adverse events observed, select **No**.
If it is not known if there were any serious adverse events observed, select **Unknown**.
If there were serious adverse events observed, select **Yes** and specify details of each adverse event in sub-questions.
27.1. ICD code:
Indicate ICD code of the adverse event. The ICD codes can be found on the WHO ICD website.

27.2. Specify:
Specify details of the adverse event.

27.3. Onset date:
Report the onset date that the adverse event was observed.

27.4. ICD version used:
Report which ICD version was used for this reporting.

Donor behaviour

28. 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.

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: