Donor Registration

Guide to the completion of the EBMT data collection form: DONOR_REGISTRATION_v1.0

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EBMT Registry

EBMT Clinical Research & Registry Department

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The donor registry

The EBMT Registry has a separate section, the Donor Outcome Registry, where donor outcome data is reported. Donor outcome data is not linked to the recipient's registration due to privacy regulations.

Some minimal information on donations is collected inside the recipient (patient) events; exact data fields depend on donor consent to share data with EBMT. Information collected during recipient (patient) events should not be considered as donor outcome reporting

For more information on accessing the donor outcome registry, see the registry manual.

This manual describes the registration process for donors through donor registries. For information on registering donors in relation to allogeneic transplants, see the allogeneic HCT manual.

The reporting of Donor outcome Data is done through 3 data collection forms:

- Donor registration form;
- Short-term follow-up report on donation procedure and up to 30 days after;
- Long-term follow-up report after the last donation procedure.

All forms, together with this manual can be downloaded from the Registry tab of the EBMT website at: https://www.ebmt.org/registry/data-collection

Introduction

A donation procedure is defined as a procedure where the objective is to collect an adequate number of therapeutic cells (e.g. hematopoietic cells or leukocytes) to be used in another individual.

The donation procedure starts with the first injection of a mobilising agent, the start of anaesthesia, or the start of apheresis (in the case of non-stimulated leukapheresis, e.g., for DLI). Even if the preparative actions (i.e, the start of injections, apheresis, or anaesthesia) are stopped prematurely (due to donor or recipient reasons), the activity fulfils the definition of a donation procedure, and the donor should be registered and followed.

Donor Registration

This form should be filled out for every new donor to be registered in the EBMT Donor Outcome Registry.

Informed consent

1. Did the donor consent to having their data submitted to EBMT?

Answer **Yes** if the donor or their legal guardian have signed the informed consent form and consent to the donor's data being reported to and processed by the EBMT Registry. Answer **No** if the written consent was not received or given.

If the answer to this question is **No**, the donor cannot be registered and/or followed-up in the EBMT Donor Outcome Registry.

2. Date of informed consent:

Indicate the date that informed consent was given (with a signed informed consent form) by the donor or their legal guardian.

3. Is your centre using the EBMT consent form?

Answer **Yes** if your centre is using the EBMT Donor Consent form published at the EBMT website (see website).

Answer **No** if your centre is using any other form than published at the EBMT website, this includes your own Informed Consent Form.

4. Did the donor consent to data sharing with health authorities and/or researchers?

This can be answered if the EBMT consent form has been used.

Indicate whether the donor or their legal guardian consent to the donor's personal data, including minimally identifiable data, in the EBMT Registry may be shared with health authorities and researchers across scientific or clinical institutions. Hereby, it is provided that an adequate level of protection for donor's privacy is applied or that sufficient contractual safeguards are arranged if this data is to be sent outside the European Economic Area.

If the answer is **No** the data cannot be used in joint studies of EBMT working parties with health authorities (unless there is a legal obligation) and/or other researchers or clinical institutions.

5. Did the donor consent to data sharing with HTA bodies/reimbursement agencies?

This can be answered if the EBMT consent form has been used.

Indicate whether the donor or their legal guardian consents that the donor's pseudonymised data in the EBMT Registry may be shared with national health authorities and HTA bodies/reimbursement agencies. Hereby, it is provided that an adequate level of protection for the donor's privacy is applied or that sufficient contractual safeguards are arranged if the donor's pseudonymised data is shared outside the European Economic Area.

6. Did the donor consent to their medical records being reviewed?

This can be answered if the EBMT consent form has been used.

Indicate whether the donor or their legal guardian consents to monitors and auditors from the EBMT and regulatory authorities reviewing the donor's medical records in accordance with applicable laws and under full confidentiality.

Donor data

7. Donor Identification:

7.1. Donor number/ID:

Provide the donor number or donor ID/code.

The Donor number/ID is used by the collection centre or centre responsible for donor follow-up to uniquely identify this donor. It must be unique in the centre, and should be sufficient to identify the donor within the hospital environment. The number should not be liable to change. If a donor provides a second donation, no new number should be assigned: the same unique number for this donor should be used when registering subsequent donation follow-up.

If the donor is being followed-up by different centres, each centre shall give the donor their own unique Donor number/ID. It is to be noted in the header of each paper version of the EBMT data collection form.

7.2. Global registration for donors (GRID): (Only for unrelated donors)

Provide the GRID of the unrelated donor. The GRID is used in the format of 19 characters, starting with 4 figures with the ION (e.g. 9999 0000 1234 5678 930) (1).

If the GRID is not assigned at the time of registration, please update this field as soon as the information becomes available.

8. Initials:

Enter only one letter as the initial of the first name of the donor followed by one letter as the initial of the surname of the donor (e.g.: Madhu Gupta should be written as M/G, John Peters should be written as J/P).

In case of complex or multiple names or surnames, the donor's preference should be always asked to identify two letters indicating the initials (e.g.: Sarah DiAmico may choose to have S/D or S/A based on donor preference, Maria Silvia Jose Mata should be written as M/J if the donor prefers Maria as the first name and Jose as the surname).

Note: Correct and consistent indication of initials is extremely important in order to avoid donor duplication in the database, it ensures the record can be traced even if the donor remains anonymous.

9. Date of birth:

The year of birth is a compulsory field, while the month and date fields are strongly recommended to be entered.

Note: *The date of birth is important information used to avoid donor duplication in the system. Failure to provide the full date of birth (with year, month, and date) due to legal, ethical, or any other reason will increase the chances of the same donor being registered multiple times.*

10. Sex (at birth):

Indicate if donor sex at birth is **Male** or **Female** by ticking the correspondent check box.

Bibliography

1. Neller, Joachim Klaus, Paul Ashford, Caroline van Veen, and Andreas Humpe. 2017. “Global Registration Identifier for Donors (GRID) of Hematopoietic Stem Cells: Road to Automation and Safety.” *Transfusion Medicine and Hemotherapy: Offizielles Organ Der Deutschen Gesellschaft Fur Transfusionsmedizin Und Immunhamatologie* 44 (6): 407.