Introduction to the EBMT Registry Completion Guidelines

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EBMT Registry

EBMT Clinical Research & Registry Department

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1. Introduction

This document describes the completion guidelines for the forms of the core dataset in the EBMT Registry. This document is not a manual for the EBMT Registry itself. The intended audience for this document is users that want to collect and submit data to the EBMT Registry.

The previously used Med A/B forms have undergone a revision. As a result of this process, a pool of new forms was created, from which data managers should pick the forms relevant to a specific time point or situation within the patient's treatment or life. The new forms can be divided into the core dataset and the extended dataset. At the moment or writing this document, only the core dataset is available.

- **Core dataset:** this is the minimum essential data that must be provided by all member centres for their consenting patients. The current manual is only focusing on the core dataset.
- **Extended dataset:** this is additional information that can be provided by centres to keep more details on a patient's medical history, or if the EBMT working party requests this information for a specific study. It includes items with more detailed questions that are relevant to most studies conducted by EBMT Working Parties. Data from the extended dataset is collected through a number of additional forms and can only be entered in addition to the core dataset. **Extended dataset collection as a functionality is not available in the first release of the EBMT Registry and will be added in later versions of the application.**

2. Data entry process

The process of patient' data collection can be described in the following steps:

1. A patient requiring a hematopoietic cell transplantation, cell therapy and/or immunosuppressive treatment (for bone marrow failures) is identified in a centre.
2. The patient then signs an informed consent form and consents to having their data shared with the EBMT.
    - If the answer is No, only anonymous data can be entered into the system (see *Anonymous events section*).
    - If the answer is Yes, proceed to the next step.
3. The centre's data manager checks if the patient is already registered in the system or not:
    - If the answer is yes, the data should be added to the existing patient record. The Patient registration form should not be completed again.

- If not, patient can be registered in the EBMT Registry (see *Patient Registration Form*).

4. The patient registration form is completed and submitted.
5. The relevant diagnosis form needs to be selected and completed.
6. The relevant treatment form (HCT/CT/IST) shall be selected and completed, together with the Disease status at HCT/CT/IST form.
7. The relevant follow-up forms need to be completed in due time (100 days, and annually)

Additionally, there is the 'non-indication diagnosis' form. This can be used to register a previous diagnosis from which the indication diagnosis might have been transformed, or at follow-up to register secondary malignancies.

2.1. Consent

Completing the ***Patient informed consent form*** should always be the first step in the process of patient data collection. The patient or their legal representative must sign the form in order for the patient data to be entered into the EBMT Registry. Please refer to the EBMT website: **https://www.ebmt.org/registry/informed-consent-form-templates.** If the patient did not consent but reporting is mandatory, the information can be completed as an anonymous event (see 2.1.1)

The ***Donor informed consent form*** should be collected to report donor-related data. The donor or their legal representative must sign the form in order for the donor data to be entered into the EBMT Registry. Please refer to the EBMT website: **https://www.ebmt.org/registry/informed-consent-form-templates.** The scope of data to be reported will differ if the donor does not provide their consent, which is marked in the affected data collection forms using an * (asterisk).

2.1.1. Anonymous events for non-consenting patients

In cases where a patient did not consent to sharing their data with EBMT, patient data cannot be entered into the EBMT Registry. Only minimal data on the performed treatment for non-consenting patients may be entered to report the activities of the centre without patient reference. For instructions on how to enter anonymous events, consult the user manual.

2.2. Data collection forms

In the process of data collection and reporting, data managers will use the following set of forms:

- **Patient informed consent** - this should always be the first form to be completed in order to start entering data. This form only needs to be completed when a new patient is registered.

- **Patient registration** - this form is submitted only once for each patient to register them in the EBMT Registry database.
- **Indication diagnosis** - there is a set of indication diagnosis forms covering information about specific disease the main treatment to be used for. The indication diagnosis form refers to the diagnosis that was the indication for the HCT, CT or IST. The diagnosis forms can be found in the diagnosis category on the EBMT website and EBMT Registry.
    - **Non-indication diagnosis** - this is a form to be filled in order to provide additional information about previous or secondary diseases of the patient that may in some way affect general health conditions of the patient and/or influence the outcomes of the treatment and thus should be taken into account while analysing. The non-indication diagnosis form should be completed when requested on one of the data collection forms (e.g. in the case of a previous malignancy) and can be found in the diagnosis category on the EBMT website and EBMT Registry.
- **Treatment** (Day 0) - there is a set of treatment forms to collect the information about each type of the treatment of interest for the EBMT. It currently includes separate forms for autologous HCT, allogeneic HCT, IST and CT. For allogeneic treatments donor informed consent is required to share some of donor-related data, which is marked in the respected forms. The treatment forms can be found in the treatment category on the EBMT website and EBMT Registry.
- **Disease status at HCT/CT/IST** (Day 0) - this is a form that must be filed together with the specific treatment form. This form can be found with the treatment forms.
- **Follow up** - there is a set of follow up forms specific for each treatment type. Data managers should note that the follow up process and the number of forms is different depending on the treatment type. It is described in detail further in this document. The follow up forms can be found in the follow up category on the EBMT website and EBMT Registry.

2.3. Timing in data submission

Once the patient has been registered in the EBMT Registry database, the following timelines should be respected.

The **indication diagnosis form** should be submitted into the EBMT Registry database when:

- In case of planned CT treatment, the respective indication diagnosis form should be reported when the centre submits the order for the cellular therapy to the market authorisation holder or the patient undergoes cell collection to procure the starting material.

- If a patient is planned to undergo an HCT, the relevant indication diagnosis form should be completed when the HCT is registered in the EBMT registry.

Day 0 is the term used to mark all **treatments** and **disease status HCT/CT/IST forms**. It highlights for the data managers to report these two forms as soon as possible after the treatment took place.

Follow-up should be submitted based on an identified schedule:

2.3.1. HCT

The first follow-up that needs to be recorded in the EBMT Registry is the 100-day assessment. The data on this assessment should reflect the patient's status on the day the patient was last seen, closest to 100 days post-transplant. If the patient died within 100 days, the data from the last date the patient was seen alive can be used. After day 100, follow-up is requested according to the following schedule:

- Every year, if the patient was transplanted less than 10 years ago,
- Every 2 years if the patient was transplanted 10–20 years ago
- Every 5 years if the patient was transplanted more than 20 years ago.

2.3.2. CT

The first follow-up that needs to be recorded in the EBMT Registry is the 100-day assessment. The data on this assessment should reflect the patient's status on the day the patient was last seen, closest to 100 days after infusion. If the patient died within 100 days, the data from the last date the patient was seen alive can be used. Subsequently, a 6-month follow-up assessment needs to be completed, or earlier if the patient died within 6 months. After this, the follow-up is requested according to the following schedule:

- Every year, if the patient was transplanted less than 10 years ago,
- Every 2 years if the patient was transplanted 10–20 years ago
- Every 5 years if the patient was transplanted more than 20 years ago.

2.3.3. IST

The first follow-up that needs to be recorded in the EBMT Registry is the 100-day assessment. The data on this assessment should reflect the patient's status on the day the patient was last seen, closest to 100 days after the immunosuppressive treatment took place. If the patient died

within 100 days, the data from the last date the patient was seen alive can be used. After this, an annual submission of follow-up data is required for IST.

In the case of multiple HCT, CT, or IST treatments only the follow-up of the last treatment given needs to be submitted according to the relevant follow-up schedule. This is regardless of the number of treatments the patient may have received. As soon as a patient gets a new treatment, the follow-up schedule starts again for that treatment.

For example, if a patient had a CT and 2 years later gets an HCT, from the HCT onwards only the HCT follow-up form needs to be completed according to the follow-up schedule.

2.4. Mandatory fields

It is essential to ensure the accuracy and usability of data entered into the EBMT Registry database. Thus, most fields are considered mandatory for completion, a few may be optional. Optional fields are always marked as such. No data items should be left blank unless specifically stated in the definition.

No fake data should be entered.

2.5. Fields requiring a date

All fields requiring a date should be completed in full in the format YYYY/MM/DD: 4 digits representing the year, followed by 2 digits representing the month, followed by 2 digits representing the day, unless stated otherwise in the definition.

If an exact date is not known for the patient or donor date of birth it is possible to enter a partial date (e.g. 2002/02 or 2002), but the year of birth is ***mandatory*** and cannot be left blank.

For other dates, when the exact date is not known, please follow the following logic:

- **Day is unknown**: indicate the day of the month as the 1st. Report month and year as documented in the medical record.
    - *Example: an HCT occurred in October of 2021, but the exact day in October is unknown. Report the date as 2021/10/01.*
- **Month and day are unknown:** indicate the month as January and the day as the 1st (YYYY/01/01). Report the year as documented in the medical record.
    - *Example: a patient was diagnosed in 2021, but the month and day are unknown. Report the date as 2021/01/01.*
- **Month, day, and year are unknown:** leave the date field blank and enter the date whenever this information becomes available.

2.6. Identifiers

2.6.1. Centre Identification Code (CIC)

Every transplant centre submitting data to the EBMT receives a **centre identification code**, also called CIC or ID, which consists of 3-4 digits and should be entered while submitting data. If you do not know your CIC, check it in the EBMT Registry application (it is shown both on the dashboard and in the context window) or look it up in the correspondence you have received from the EBMT. This item is essential for the proper registration of your data.

If you are not a member of the EBMT yet and want to report data, contact the EBMT at:

membership@ebmt.org

2.6.2. Unique Patient Number (UPN)

UPN (unique patient number) - the number/code used by the transplant centre or other entity to uniquely identify this patient in the centre.

2.6.3. Patient identifier/short ID

The patient identifier or short ID (EBMT short patient ID) is the ID the EBMT Registry assigns to a patient when they are created. The short ID is automatically generated and is unique across the EBMT Registry. The short ID cannot be changed.