EBMT Registry

Introduction to the EBMT Registry Completion Guidelines

General guide to the completion of the EBMT data collection forms

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EBMT Registry

EBMT Clinical Research & Registry Department

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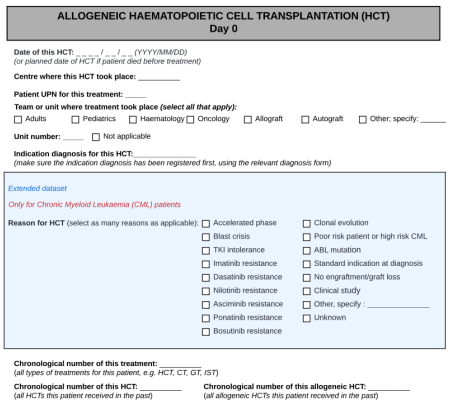
Introduction

This document describes the completion guidelines for the forms of the core and extended 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 EBMT data collection forms contain both the core dataset (shown as normal text/tables/questions) and the extended dataset (always highlighted and clearly marked) items.

• **Core dataset**: this is the minimum essential data that must be provided by all member centres for their consenting patients. The core dataset data is collected via a set of data collection forms from which data managers should pick the forms relevant to a specific time point or situation within the patient's treatment or life. All currently published EBMT data collection forms (DCFs) are part of 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. There are no extended data set DCFs currently. Data from the extended dataset is collected through a number of additional questions (data fields) in the existing DCFs which are clearly marked in the data collection forms and can only be entered in addition to the core dataset items . Extended dataset collection as a functionality was added in 2.6 and later versions of the EBMT Registry application.



ALLOGENEIC HAEMATOPOIETIC CELL TRANSPLANTATION (HCT)
Day 0

Date of this HCT: _ _ _ _ / _ _ / _ _ *(YYYY/MM/DD)*
(or planned date of HCT if patient died before treatment)

Centre where this HCT took place: _____

Patient UPN for this treatment: _____

Team or unit where treatment took place *(select all that apply)*:
☐ Adults ☐ Pediatrics ☐ Haematology ☐ Oncology ☐ Allograft ☐ Autograft ☐ Other; specify: _____

Unit number: _____ ☐ Not applicable

Indication diagnosis for this HCT: _____
(make sure the indication diagnosis has been registered first, using the relevant diagnosis form)

Extended dataset

Only for Chronic Myeloid Leukaemia (CML) patients

Reason for HCT (select as many reasons as applicable):
☐ Accelerated phase
☐ Blast crisis
☐ TKI intolerance
☐ Imatinib resistance
☐ Dasatinib resistance
☐ Nilotinib resistance
☐ Asciminib resistance
☐ Ponatinib resistance
☐ Bosutinib resistance
☐ Clonal evolution
☐ Poor risk patient or high risk CML
☐ ABL mutation
☐ Standard indication at diagnosis
☐ No engraftment/graft loss
☐ Clinical study
☐ Other, specify : _____
☐ Unknown

Chronological number of this treatment: _____
(all types of treatments for this patient, e.g. HCT, CT, GT, IST)

Chronological number of this HCT: _____
(all HCTs this patient received in the past)

Chronological number of this allogeneic HCT: _____
(all allogeneic HCTs this patient received in the past)

Image 1. Example of core dataset and extended dataset items marked in a DCF. The questions on the blue background belong to the extended dataset.

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/patient-informed-consent. If the patient did not consent, but reporting is mandatory, the information can be completed as an anonymous event.

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. This is applicable for both donors in allogeneic HCTs/CTs and the donor outcome registry. Please refer to the EBMT website for more details: https://www.ebmt.org/registry/donor-informed-consent. The scope of data to be reported in EBMT Registry will differ if the donor does not provide their consent, which is marked in the affected data collection forms using an * (asterisk).

The centres are responsible for obtaining the patient and donor consent and to provide evidence of the consent acceptance following GDPR and their local regulations.

If a patient consented to share data with EBMT and signed ICF in one centre, the date of such ICF signed is recorded in the EBMT Registry as the first date of informed consent. The first day of consent must not be changed in this case and cannot be modified in the EBMT Registry by the users, because the first consent date is the date when the relation patient-EBMT or donor-EBMT was authorised and started. EBMT as a Data Controller of the EBMT Registry shall be able to provide evidence of the first day in order to be able to show that the data has been collected lawfully.

If later the patient moves to another centre for a new treatment or follow up, the patient should sign a new ICF. Once a new centre receives access to the existing patient record, data manager from the new centre should enter the date of the most recent signed ICF into the dedicated data field, check and update the latest answers to the consent-related sub-questions accordingly.

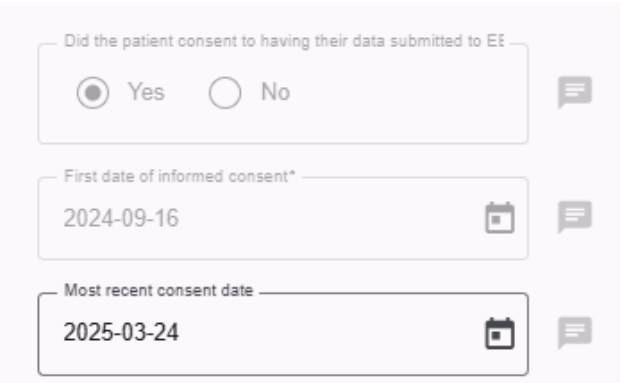


Image 2. Example of the *First date of informed* consent and the *Most recent consent date* fields in the EBMT Registry

Patients and/or donors may sign new informed consent form (re-consent in order to change answer to some of the questions), this is the centre responsibility to update consent-related data of the patient/donor in the EBMT Registry and to provide the date of the most recent informed consent signed.

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 reporting patient identifiable data.

Patient Registry

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, gene 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 the patient was previously registered by another centre, the data manager should follow a process described at EBMT website as ***Access to patients given a prior treatment in another centre.***

● If not, the 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.

Data managers may consult the ***List of disease classifications*** available under *Manuals and Reference Documents* section on EBMT website.

6. The relevant ***treatment form*** (HCT/CT/GT/IST) shall be selected and completed, together with the ***Disease status at HCT/CT/GT/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.

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 the specific disease the main treatment is given for. The indication diagnosis form refers to the diagnosis that was the indication for the HCT, CT, GT 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, CT and GT. For allogeneic treatments donor informed consent is required to share some of donor-related data, which is marked in the respective forms. The treatment forms can be found in the treatment category on the EBMT website and EBMT Registry.

- **Disease status at HCT/CT/GT/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.

- **Treatment non-HCT/CT/GT/IST therapy** - this form must be submitted whenever there is an instruction to complete the "Treatment - non-HCT/CT/IST/GT" form on the diagnosis, main treatment or follow-up

form. The purpose of this form is to report pre-HCT/CT lines of treatment or additional lines of treatment given during the follow-up period post main treatment. The treatments can include chemotherapy or any other intervention (radiotherapy, surgery) for the indication diagnosis. The form should be completed only if the treatment was given for the disease that was the indication for the HCT, CT, GT or IST and for the following reasons: induction, bridging, relapse, progression, maintenance/preventive treatment, or consolidation. This form is only relevant for malignant diseases and Immunoglobulin-related Amyloidosis.

Timing in data submission

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

Diagnosis

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

- In case of planned CT or GT 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 procedure 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/GT/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 for each treatment type schedule

HCT

The HCT treatment form should be completed as soon as the HCT procedure took place.

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.

If there are fluctuations in the disease status during the follow-up period and the centres deem it relevant, or if the patient is discharged from the centre and/or moves to another centre, an additional report may be provided between the standard reporting schedule.

CT

The CT form should be completed as soon as the CT took place, or when it is concluded that the CT product will not be infused for whatever reason.

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.

If there are fluctuations in the disease status during the follow-up period and the centres deem it relevant, or if the patient is discharged from the centre and/or moves to another centre, an additional report may be provided between the standard reporting schedule.

GT

The GT form should be completed as soon as the GT took place, or when it is concluded that the GT product will not be infused for whatever reason.

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 GT product 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 12 months, 18 months and then annually post-GT (up to 15 years) or at time of patient death, whichever occurs first.

If there are fluctuations in the disease status during the follow-up period and the centres deem it relevant, or if the patient is discharged from the centre and/or moves to another centre, an additional report may be provided between the standard reporting schedule.

IST

The IST treatment form should be completed as soon as the HCT procedure took place.

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.

If there are fluctuations in the disease status during the follow-up period and the centres deem it relevant, or if the patient is discharged from the centre and/or moves to another centre, an additional report may be provided between the standard reporting schedule.

Multiple HCT, CT, GT or ISTs

If a patient received subsequent treatment (HCT, CT, GT or IST), it is important to submit the relevant follow-up form for the previous HCT/CT/IST/GT before reporting the new HCT/CT/IST/GT treatment. The follow-up assessment date should reflect the period up to the start of the new treatment. This is required to capture disease status and all events between transplants/cellular therapies.

In the case of multiple HCT, CT, GT or IST treatments, only the follow-up of the most recent 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. Each time a new treatment is given, a new follow-up schedule starts again for that treatment.

For example, if a patient has a CT and 2 years later gets an HCT: a CT follow-up shall be reported and then the HCT treatment; from the HCT onwards only the HCT follow-up form needs to be completed according to the follow-up schedule.

Non HCT/CT/GT/IST treatment form

The non HCT/CT/GT/IST treatment form was introduced in version 2 of the core dataset. This form is to be submitted as core data if there is an instruction to complete the “Treatment - non-HCT/CT/IST/GT” form on the diagnosis, main treatment or follow-up form. The form is considered as mandatory for reporting and currently covers the following cases:

Lymphomas	all pre-HCT/CT lines of treatment
Chronic Leukaemias (CML and CLL)	all pre-HCT/CT lines of treatment
Cellular Therapy	all pre-CT lines of treatment for all malignant

	indication diagnoses and Immunoglobulin-related Amyloidosis
HCT Day 100 Follow-up	all post-HCT lines of treatment for all malignant indication diagnoses and Immunoglobulin-related Amyloidosis
HCT Annual/Unscheduled Follow up	all post-HCT lines of treatment administered during the follow-up period for all malignant indication diagnoses and Immunoglobulin-related Amyloidosis

If the instruction is marked as an extended dataset item then the data is volunteer for submission.

Currently it covers the following cases:

Chronic Leukaemias (PLL and Other Chronic Leukaemias)	all pre-HCT/CT lines of treatment
Plasma Cell Neoplasms	all pre-HCT/CT lines of treatment
MDS/MPN overlap syndromes	all pre-HCT/CT lines of treatment
Myeloproliferative Neoplasms (MPN)	all pre-HCT/CT lines of treatment
Myelodysplastic Neoplasms (MDS)	all pre-HCT/CT lines of treatment
Acute Leukaemias	all pre-HCT/CT lines of treatment

Treatments that should be reported via this form are previous or subsequent lines of chemotherapy, surgery, or radiation.

There is no follow-up form for non HCT/CT/GT/IST treatments.

Donor outcome 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 (patient) 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 EBMT Registry User Manual for Data Editors and Data Viewers available on EBMT website.

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.

Data entry process

The process of donors' data collection in the Donor outcome registry can be described in the following steps:

1. A donor providing material for a hematopoietic cell transplantation and/or cell therapy is identified in a centre.

2. The donor then signs an **informed consent form** and consents to having their data shared with the EBMT.

- If the answer is **No**, no data can be entered into the system.
- If the answer is **Yes**, proceed to the next step.

3. The centre's data manager checks if the donor is already registered in the system or not:

- If the answer is **Yes**, the data should be added to the existing donor record. The Donor registration form should not be completed again. If the donor was previously registered by another centre, the data manager should contact registryhelpdesk@ebmt.org**.**
- If not, the donor can be registered in the EBMT Registry (see Donor Registration Form).

4. The **Donor registration form** is completed and submitted.

5. The **Short-term follow-up** report on donation procedure and up to 30 days after form is completed and submitted.

6. The **Long-term follow-up** report after the last donation procedure.

All forms, together with the completion guidelines can be found under Donor Outcome Registry Data Collection Forms section the EBMT website at: https://www.ebmt.org/registry/ebmt-data-collection.

Mandatory fields in the core data set

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.

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.

Identifiers

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

Unique Patient Number (UPN)

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

Patient identifier/short ID

EBMT patient ID - is a unique patient identifier in the EBMT Registry that is generated automatically by the system in GUID / UUID format at the moment of patient registration in the EBMT Registry.

The patient identifier or short ID (EBMT short patient ID) is more convenient in daily use than EBMT patient ID since it consists only of the last 7 digits of the EBMT patient ID. The short ID cannot be changed.

Example: EBMT patient ID d301d005-9d75-4673-8c3e-421f619c337a, EBMT short patient ID 19c337a.