EBMT Registry

Allogeneic HCT

Day 0

Guide to the completion v2.5 of the EBMT data collection form:

AlloHCT_Day0_Core_Extended_v2.4

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EBMT Registry

EBMT Clinical Research & Registry Department

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Introduction

Please make sure you have already checked the **Introduction to the EBMT Registry Completion Guidelines** document latest version available under *Manuals and Reference Documents* section on EBMT website.

Allogeneic HCT Day 0

Allogeneic HCT (Allo-HCT) uses hematopoietic stem cells collected from another related or unrelated individual. Allo-HCT is increasingly used to treat a variety of hematologic neoplasms and nonmalignant marrow disorders (acquired and inherited), including inborn errors of metabolism.

Day 0 is considered the day of the first haematopoietic stem cell infusion if there are multiple infusions of one or several graft products over several days after the same conditioning regimen. The transplant procedure is considered to start when the conditioning regimen is initiated.

This form must be completed for all patients who received Allo-HCT. No data items should be left blank unless specifically stated in the instruction.

Date of this HCT

Report the date the transplantation took place. If the patient died before the treatment took place, report the planned treatment date.

Centre where this HCT took place

Indicate the Centre Identification Code (CIC) of the centre where the allogeneic transplantation took place. This is the centre where the infusion of the autologous HCT took place.

Patient UPN for this treatment

Report the hospital or unit's UPN (unique patient number) for the patient at this treatment.

Team or unit where treatment took place (select all that apply)

Select the team or unit where the treatment took place. Multiple options can be selected. If **Other; specify** is selected, you must give further information on the name of the team or unit where the treatment took place. For example, your team or unit name may be derived from your geographical location (e.g. south unit or north unit).

Unit number (not Other team or unit; specify)

Unit numbers have been assigned by national registries to different teams submitting data under the same CIC. This will allow data in filtered searches and exports to be team specific.

If your centre does not have separate teams with assigned unit numbers select **Not applicable**.

Indication diagnosis for this HCT

Select the disease for which the reported treatment is being given. In addition, make sure that the diagnosis has been registered first, using the relevant diagnosis form. While submitting data in the EBMT Registry web application, the user will be provided with a list of diagnoses available for the patient, from which only one option can be selected.

Extended dataset

Chronic Myeloid Leukaemia (CML)

Reason for HCT

Select the reasons for this subsequent HCT from the list (as many reasons as applicable).

Reason	**Explanation**
Accelerated phase	Definition of accelerated phase: ● Bone marrow or peripheral blood blasts 10%-19% ● Peripheral blood basophils ≥ 20% ● Presence of additional clonal cytogenetic abnormality in Ph+ cells (ACA)
Blast crisis	Definition of blast crisis: ● Bone marrow or peripheral blood blasts ≥ 20% ● Extramedullary blast proliferation (myeloid sarcoma) ● Presence of morphologically apparent lymphoblasts (>5%) warrants consideration of lymphoblastic crisis
TKI intolerance	An inability to tolerate adverse event(s) due to TKI treatment which can not be managed with dose reduction or treatment of symptoms.
Imatinib resistance	The reduction of effectiveness of treatment. This can refer to a lack of haematologic, cytogenetic, or molecular response to the drug in the early stages of treatment, or the loss of response after a patient has gained a certain degree of therapeutic response.
Dasatinib resistance	
Nilotinib resistance	
Asciminib resistance	
Ponatinib resistance	

Bosutinib resistance	
Clonal evolution	The result of the cytogenetic analysis shows that there is at least one new chromosomal abnormality (or several) in addition to the t(9;22).
Poor risk patient or high risk CML	High risk CML (HR-CML) comprises patients resistant to at least 2 TKI, those harbouring BCR::ABL1 mutations, particularly the T315I mutation, patients carrying major route cytogenetic abnormalities or patients with accelerated phase CML (AP-CML) progressing from chonic phase CML (CP-CML). High ELTS score may be considered also.
ABL mutation	Normally in CML, there is no mutation of the ABL1 gene, but it is attached to another gene called BCR. Together they form a fusion gene called BCR::ABL1. However, during treatment with Imatinib and other TKIs it is relatively common to develop one or more mutations in the ABL1 gene. Mutations are important because they can make the BCR::ABL1 resistant to the therapeutic effects of Imatinib and other TKIs.
Standard indication at diagnosis	The HCT is part of the standard protocol of the centre.
No engraftment/graft loss	The patient had a prior HCT and there was no engraftment or the graft was lost during the follow up.
Clinical study	The patient is enrolled in a clinical study and treated according to protocol.
Other, specify	Use this to indicate non listed reasons like, for example, "Patient's preference".

Table 1. Reasons for HCT for chronic myeloid leukaemia and their use cases for reporting data in the EBMT Registry.

Chronological number of this treatment

Indicate the chronological number of the current treatment among other treatments (HCT, CT, GT, IST) received by the patient throughout his/her lifetime, regardless of whether the previous treatments have been performed in your centre or other centres. It is NOT the serial number of the current treatment within all the treatments performed in your centre, and it is NOT the number of the treatments that this patient has received in your centre only.

The information about the chronological number can be obtained from the patient's medical history record.

Chronological number of this HCT

Indicate the chronological number of the current HCT among other HCTs, both allogeneic and autologous, that this patient has received throughout his/her lifetime, regardless of whether the previous HCTs have been performed in your centre or other centres. It is NOT the serial number of this HCT within all the HCTs performed in your centre, and it is NOT the number of the HCT that this patient has received in your centre only.

The information about the chronological number can be obtained from the patient's medical history record.

Chronological number of this allogeneic HCT

Indicate the chronological number of the current allogeneic HCT among other allogeneic HCTs that this patient has received throughout his/her lifetime, regardless of whether the previous allogeneic HCT has been performed in your centre or in other centres. It is NOT the serial number of this allogeneic HCT within all the allogeneic HCTs performed in your centre, and it is NOT the number of the allogeneic HCT that this patient has received in your centre only.

The information about the chronological number can be obtained from the patient's medical history record.

Chronological number of the treatment is >1

The following section should only be filled out if the number indicated in question ***Chronological number of this treatment*** of the current form is more than 1.

Submit the relevant follow-up form for the previous HCT/CT/IST/GT using the follow-up assessment date before reporting this allogeneic HCT. It is required to capture disease status and all events between transplants/cellular therapies.

Reason for this HCT

Select the main reason for this subsequent HCT from the list.

Indication diagnosis - if the patient required this subsequent HCT as part of planned disease management (e.g., as part of a planned multiple graft program).

Relapse/progression after previous treatment (HCT/CT/GT/IST) - If the patient required this subsequent HCT as a result of a return of signs and symptoms of a disease after a period of improvement observed post the previous treatment.

Complication after previous treatment (HCT/CT/GT/IST) - If the patient required this subsequent HCT as a result of a complication (other than relapse/progression) that developed after the previous treatment.

Primary graft failure - If the patient required this subsequent HCT as a result of a failure of initial engraftment of donor haematopoietic cells.

Secondary graft failure - If the patient required this subsequent HCT as a result of a loss of donor haematopoietic cells following initial engraftment.

Secondary malignancy - If the patient required this subsequent HCT as a result of a secondary malignancy.

If the reason the patient required this subsequent HCT is not available in the list, check the **Other** box and report the reason in the textbox in English.

Date of the last main treatment before this one

Report the date of the previous HCT/CT/GT/IST treatment before this allogeneic HCT.

Type of the last main treatment before this one

Select the type of the previous HCT/CT/GT/IST treatment before this allogeneic HCT from the list.

It can be: autologous HCT, allogeneic HCT, cellular therapy, immunosuppressive treatment (BMF only) or gene therapy.

Was the last main treatment performed at another institution?

Indicate if the previous HCT/CT/GT/IST treatment was performed in another institution than the one performing this allogeneic HCT. If the answer is **Yes** also report:

CIC (if known)

Report the CIC of the centre where the previous treatment took place (if known).

Name of institution

Report the name of the centre where the previous treatment took place.

City

Report the city where the centre performing the previous treatment is located in.

Donor & Graft

Is this HCT part of a (planned) multiple (sequential) graft program/protocol?

Sometimes patients are entered into protocols that include more than one transplant. A typical example might be the use of an autologous transplant to prepare the patients for a non-myeloablative (reduced intensity) allograft. In this case, the allograft would be number 2 out of 2 pre-programmed transplants. In this example, the 'AUTOLOGOUS HAEMATOPOIETIC CELL TRANSPLANTATION (HCT) - Day 0' form and 'DISEASE STATUS AT HCT/CT/GT/IST - Day 0' form should have been completed for the first transplant.

Some patients may have received a transplant (autologous or allogeneic) prior to this procedure as part of earlier disease management. In this case, the current transplant is not part of a multiple-graft program.

A subsequent transplant that has been programmed to happen only if an intermediate event takes place (ie: relapse) should not be considered a part of a multiple transplant program.

Select **Yes** if the patient received the current allogeneic HCT as a part of a (planned) multiple (sequential) graft program/protocol. Please also enter **Yes** when the current allogeneic HCT was part of a planned multiple graft program even in those cases where the 2nd HCT did not take place (for whatever reason). Otherwise, select **No**.

Chronological number of this HCT as part of multiple (sequential) graft program/protocol for this patient

If you answered **Yes** to the previous question, also indicate the chronological number of the current allogeneic HCT in the program.

If this is the first allogeneic HCT for this patient, complete the patient HLA section in the database. The list of HLA options is regularly updated in the EBMT Registry using the IPD-IMGT/HLA database.

IMPORTANT NOTE:

LABORATORY RESULTS WITH HLA TYPING must be added to the database for all the patients.

When you enter data into the database please ensure the HLA typing is complete.

Please consult the HLA data entry manual, https://hla.alleles.org/nomenclature/index.html and https://hml.nmdp.org/MacUI/ for more details on HLA.

Multiple donors (including multiple CB units)

Indicate whether products used in this transplant belonged to more than one donor by selecting **No** or **Yes**. If you answered **Yes**, also report the **Number of donors**. The number should never be equal to 1.

This can be the case when the transplant involves cord blood (CB): multiple CB units (CBU) being used in one HCT is not rare.

IMPORTANT NOTE:

The form provides space to fill in up to 1 donor. If the patient had more than 1 donor in the current transplant, copy the next section as many times as necessary and fill in the information for each individual donor separately, indicating the sequential number assigned to each donor.

Donor Information

Did the donor consent to having their data in the EBMT registry?

Centres should download and fill in the Donor Consent Form in the appropriate language for each of their donors, as the law requires that the donor consents to the data being transferred to the EBMT.

EBMT shall provide the Informed Consent Form to the participating sites for data reporting to EBMT. The reporting centre shall be responsible for ensuring that the Informed Consent Form is in compliance with applicable laws and meets the minimum requirements as indicated by the Informed Consent templates on this web page. No centre is exempt from obtaining donor consent before submitting data to the EBMT.

Indicate if the donor consented to share the data with the EBMT registry by selecting **Yes** or **No**. If you do not know the status of consent, or the donor did not want to share their data, select **No**.

If the donor did not consent or consent is unknown and no is elected, only data items marked with an asterisk (*) can be filled out.

Date of birth

Indicate the donor's date of birth.

The year of birth is a compulsory field (*), while month and date fields are strongly recommended ones.

NOTE:

The date of birth is important information used to avoid patient duplication and accurately calculate the donor's age at the time of donation. At least the year of birth is mandatory. Failure to provide the full date

of birth (due to legal, ethical, or any other reason) will result in increasing the chances of donor duplication in the system.

*Age at time of donation

If it is not possible to Indicate the donor's date of birth, Indicate the age of the donor (in years) at the time of the donation procedure. This data item is optional.

*Age in months

If it is not possible to Indicate the donor's date of birth and the donor was younger than 2 years, indicate his/her age at the time of the donation procedure in months. This data item is optional. Skip if the source of stem cells is cord blood.

*Sex (at birth)

Indicate the donor's biological sex as **Male** or **Female**.

The sex of the donor, which you may find in the histocompatibility forms, is important in relation to Graft versus Host Disease (GvHD).

Donor Identification

It has become increasingly important from the clinical and the legal point of view, to be able to use joint information for the patient and donor(s) pair for each transplant. For this reason, it is very important that, while keeping anonymity, the donor data can be traced. This can only be done if the unique identification codes for the donors are stored.

It is for this reason that the EBMT is requesting the information below. Although this may look unnecessary, it cannot be stressed enough how important it is to be able to identify the correct set of data and, given the current situation, where there are no agreements on how to identify donors uniquely, it is best practice to collect all possible unique identifications.

Donor ID given by the treating centre (mandatory)

If the donor comes from an unrelated donor registry, please enter the code/number given to the donor by the donor registry. If the donor is related, please enter the code/number by which the donor is identified in your centre. This data item is very important and hence marked as mandatory.

Global registration identifier for donors (GRID)

Indicate the GRID of the donor. Global Registration Identifier for Donors (GRID) was developed by WMDA to ensure the secure, reliable, and unambiguous assignment of donors (1).

The GRID standard is a 19-character donor identifier composed of three elements: Issuing Organization Number (ION), Registration Donor Identifier, and Checksum as shown in figure 1.

Figure 1. ION code example.

ION code of the Donor Registry or Cord Blood Bank (mandatory)

The ION identifies organisations that issue GRIDs and is assigned by ICCBBA in its role as an issuing agency under ISO 15459. A unique random ION is assigned to each issuing organisation. The ION is a 4-digit number between 1000 and 9999. It shall be encoded and interpreted by reference to the ICCBBA GRID Issuing Organization Database published and maintained by ICCBBA on the ICCBBA Website. The ION shall be used as the first 4 characters within a GRID to create global uniqueness and may also be used for other purposes (e.g., databases) to identify organisations that assign GRIDs.

WMDA list is available at: https://share.wmda.info/display/WMDAREG/Database.

This list also contains some, but not all, Cord Blood banks.

Enter the ION code in the form. For reference, you can find a conversion table of the ION codes and former BMDW codes in our Document Center. This data item is very important and hence marked as mandatory.

EuroCord code for the Cord Blood Bank (if applicable)

EuroCord also keeps a list of Cord Blood Banks. If you know the code given by EuroCord, indicate it here.

Name of Donor Registry or Cord Blood Bank

Enter the name of the donor registry, or, in the case of cord blood, the name of the cord blood bank in full.

PLEASE NOTE that most countries are now centralised under one ION code (e.g.: the UK are under Antony Nolan, but donations can take place under any UK donor registry), so if you know the Name of the Donor Registry, please write it in this field, after you provide the ION code.

Donor ID given by the Donor Registry or Cord Blood Bank

It is an identification given by the Donor Registry or the Cord Blood Bank to the donor.

NOTE:

The CIBMTR and NMDP have requested that the donor ID given by the registry be entered as a number only with retaining the leading zero (if applicable).

Therefore, do not enter dashes between numbers, do not add “NMDP” or other characters to the beginning of the donor id, and do not drop leading zeroes. Examples of common mistakes and how to resolve them are presented in table 2.

Incorrect	**Correct**	**Explanation**
0257-8376-2	025783762	No dashes between numbers
NMDP0323-4119-0	032341190	No additional characters, no dashes between numbers
81706343	081706343	Keep leading 0’s
US033941345	033941345	No additional characters
0699-30685	069930685	No dashes between numbers

Table 2. Examples of mistakes in adding the donor ID.

The reason for this is to ensure data integrity and facilitate the identification of the donor when EBMT shares the data to the CIBMTR for those centres that have requested it.

Patient ID given by the Donor Registry or Cord Blood Bank

It is an identification given by the Donor Registry or the Cord Blood Bank to the recipient. Although this is currently an optional field, it is extremely important information, which helps in identifying the correct set of data. It is always the best practice to collect all possible unique identifications.

*Donor blood group

Indicate the blood group of the donor by marking if it is **A**, **B**, **AB** or **O**.

*Donor rhesus factor

Indicate if the donor's rhesus factor (Rh) is **Negative** or **Positive**.

*Donor EBV status

Epstein-Barr virus (EBV) is a widespread human herpesvirus (HHV4), infecting the majority of children, that establishes lifelong latent infection in the host memory B cells. This virus accounts for post-transplantation lymphoproliferative disorder (PTLD), one of the most serious allogeneic hematopoietic cell transplantation complications.

Report the laboratory result of the EBV antibody testing of the donor as **Negative** or **Positive** (positive EBV VCA IgG or EBNA assay results). If the testing was not performed, select **Not evaluated**. If the results of the testing are not known, report **Unknown**.

*Donor CMV status

Human cytomegalovirus (CMV) is a betaherpesvirus in the same family as human herpesvirus-6 and -7. Like the other herpesviruses, CMV remains in the human body after primary infection for life. In allogeneic HCT recipients, the most important risk factors for CMV disease are the serologic status of the donor and recipient. Approximately 30% of seronegative recipients transplanted from a seropositive donor (D+/R-) develop a primary CMV infection.

Report the laboratory result of the CMV antibody testing of the donor as **Negative** or **Positive** (positive CMV IgG assay result). If the testing was not performed, select **Not evaluated**. If the results of the testing are not known, report **Unknown**.

*Is donor heterozygous? (Sickle cell disease only)

Report if the donor is an HbS trait carrier based on the blood test results by selecting either **No** or **Yes**. This question should be answered only if the patient was diagnosed with Sickle Cell Disease.

*Is donor a carrier for X-linked disease? (Inborn Errors only)

Report if the donor is a X-linked trait carrier based on the blood test results by selecting either No or Yes. This question should be answered only if the patient was diagnosed with Inborn Errors. If the testing was not performed, select **Not evaluated**. If the results of the testing are not known, report **Unknown**.

*Did this donor provide more than one stem cell product

For each donor indicate whether the donor provided more than one stem cell product.

One stem cell product - cells were obtained using the same mobilisation cycle and collection method regardless of the number of collection days.

Multiple stem cell products - cells were obtained using more than one mobilisation technique/cycle, and/or collection method.

If the donor provided one product only (e.g. PB), answer **No** and fill in details on "Donor 1" - "Product Number 1".

If more than one product was obtained from the same donor (e.g. BM and PB), answer **Yes** and fill out details on "Donor 1" - "Product 1" and "Donor 1" - "Product 2". In addition, specify the **Number of different stem cell products from this donor**.

IMPORTANT NOTE:

The form provides space to fill in up to 2 products per donor. If there were more than 2 products per donor, copy the relevant section as many times as necessary and fill in the information for each product separately.

*Source of stem cells

Indicate the stem cells' source by selecting only one option from the list. If the source of the stem cells is not available in the list, check the **Other** box and specify the source in the textbox in English.

*Graft manipulation ex-vivo including T-cell depletion

An ex-vivo (same as *in vitro*) manipulation is a "treatment of the graft in the laboratory". Graft manipulation is performed to define and optimise the volume and cellular composition of stem cell sources like apheresis products, bone marrow, or umbilical cord blood.

Indicate if the graft was manipulated ex-vivo by selecting either **No** or **Yes**. If answered **Yes**, select the manipulation type from the list of options.

T-cell (CD3+) depletion - Removal of T-cells (CD3+) from the donor graft. Depletion of T-cells (CD3+) provides almost untouched grafts with potential anti-leukaemic effectors (e.g., NK cells) enabling fast engraftment and reliable prevention of GvHD.

T-cell receptor αβ depletion - Selective depletion of T cells expressing the αβ T cell receptor. This allows for the removal of cells responsible for GvHD and PTLD but maintains haematopoietic progenitor and stem cells for engraftment (CD34+ cells), as well as cells to elicit graft-versus-tumour effect and provide anti-infective activity (such as gamma-delta T cells and natural killer cells).

B-cell depletion (CD19+) by MoAB - B-cells are depleted from the graft by using monoclonal antibodies. Please, do not record anti-CD20 antibody treatment of the patient here.

NK cell depletion by MoAB - NK cells are depleted from the graft by using monoclonal antibodies.

CD34+ enrichment - Positive selection of CD34 cells. The manipulation provides a graft with a very low number of T cells and therefore allows to avoid GvHD very effectively.

Ex vivo expansion of CD34+ cells - Culturing of CD34+ cells outside the body to increase cell numbers.

If ex vivo expansion of CD34+ cells is ticked, specify the method:

- **UM171 (Zemcelpro; dorocubicel)**
- **Nicotinamide (NAM) (NiCord/omidubicel)**
- **Notch ligand-based expansion**.

Genetic manipulation - This is a procedure by which techniques of gene transfer/transduction are used to alter the structure and characteristics of genes in the graft before the cell infusion.

If the manipulation type is not available in the list, check the **Other** box and specify the manipulation procedure in the textbox in English.

Also, select **No** if the manipulation consisted of plasma and/or red cells and volume reduction.

Report only manipulations performed at the transplant centre. If the cells, particularly, cord blood cells have been manipulated before reaching the transplant centre, these manipulations should not be reported here.

NOTE:

Alemtuzumab (Campath) is sometimes added to the bag containing the cells, and gets infused into the patient together with these same cells during the transplantation. This treatment is known as “Campath in the bag”. In this case, the difference between ex vivo and in vivo treatment is blurred. To avoid double reporting of the same treatment, we advise that, until further notice, “Campath in the bag” is not reported here. Hence, do not select **T-cell (CD3+) depletion**, if “Campath in the bag” was used.

Extended dataset

Infused cell counts

Cell counts for this product

Cell counts may be performed on the stem cell product at various time points and sometimes it is difficult to decide which should be reported as the “cells infused”. First, a count may be done immediately after collection. If the stem cells are infused directly into the patient this would also be the number of ‘cells infused’. If the stem cells are manipulated in the laboratory in any way, e.g. removal of red cells or plasma because of ABO incompatibility; or cells are selected for subpopulations such as CD34+ cells, then the count will be repeated after completion of the manipulation. If the cells were then infused into the recipient this would then be the number of ‘cells infused’. If the cells were cryopreserved it is possible that some of the cells might be lost during the process of freezing. At the time of thawing a further count would be performed and then this would be the number of ‘cells

infused'. However, when cryopreserved cells are thawed they often have to be given immediately to the patient and it is not always possible to obtain an accurate count. Ask your physician for the procedure in your own laboratory. If you cannot provide a count that accurately reflects the number of 'cells infused' then record the count you have available but make a note of the particular circumstances.

Report the total number of nucleated cells, CD34+, and CD3+ cells after thawing and manipulation (if either or both occurred).Select **Unknown**, if the count number is unavailable and select **Not evaluated** if the cell count was not performed.

- **Nucleated cells** consist of all cells, minus erythrocytes
- **CD34+ cells** are an immunological description of stem cells.
- **CD3+ cells** are an immunological description of T lymphocytes.

For each cell type, report the cell counts per kg body weight of the recipient, and report the **unit** of measurement (x10^5/kg, x10^6/kg, x10^7/kg or x10^8/kg).

*Was the graft cryopreserved prior to infusion?

Indicate whether the graft was cryopreserved before infusion or not.

Date of cryopreservation

If **Yes**, indicate the date of cryopreservation.

Extended dataset

Cord blood

Cord blood refers to the whole blood including hematopoietic progenitor cells collected from placental and/or umbilical cord blood vessel after the umbilical cord has been clamped.

Cell infusion method for this product

Route

Indicate the route of administration to the patient by selecting one of the options:

- **intravenous** (refers to an infusion into the veins);
- **intrabone/intramedullary** (refers to an infusion into the marrow cavity within a bone).

If the cells were infused using a different route of administration, select **Other** and specify the route of administration in English. Mark **Unknown** if this information is unavailable.

Method

Dimethyl sulfoxide (**DMSO**) or **Wash**. If another method was used, select **Other** and specify the method in English. Mark **Unknown** if this information is unavailable.

Cell viability results at HCT centre

Cell viability refers to the number of live, healthy cells in a sample and is measured using cell viability tests. Indicate if cell viability tests were performed at the HCT centre.

Tests performed after thawing of an aliquot on

For performing the cell viability tests, a (thawed) sample (also called aliquot) obtained from the cord blood unit was needed. Indicate if these viability tests were performed after thawing of an aliquot from either **contiguous segment** or **reference bag**.

- Contiguous segment - a sealed lengths of tubing integrally attached to the cord blood unit that contains a sample representative of the cord blood that may be used for testing;
- Reference bag - a separate sample bag from the cord blood unit set aside for testing or quality control.

Mark **Unknown** if this information is unavailable.

Method used

Indicate the staining method used to assess cord blood cell viability by selecting one of the options:

- 7-aminoactinomycin D (**7-AAD**);
- **tryptan blue;**
- **acridine orange-ethidium bromide (AO/EB);**
- **acridine orange-ethidium iodide**.

If another method was used, select **Other** and specify the method in English. Mark **Unknown** if this information is unavailable.

Viability of all cells

Report the percentage of viable cells. Mark **Unknown** if this information is unavailable.

Viability of CD34+ cells

Report the percentage of viable CD34+ cells. Mark **Unknown** if this information is unavailable.

*Relation between patient and donor

The outcome of HCT depends in part on the matching between the donor and the recipient for the human leukocyte antigens (HLA), encoded by a group of genes on chromosome 6; genes and products are labelled as major histocompatibility complex (MHC). The HLA system is the most polymorphic genetic region in the human genome.

A set of HLA gene alleles, called a haplotype, is inherited from each parent; therefore, the probability that a child inherits and shares both parental haplotypes with a full sibling is 25%. Such an HLA-identical sibling is still considered an optimal donor for young patients.

Indicate the type of donor by selecting one of the options:

Related - a donor who is blood-related to the patient. This includes monozygotic twins, siblings, parents, aunts, uncles, children, cousins, half-siblings, etc.

Unrelated - a donor who has no known blood relation to the patient. These donors are found through an unrelated donor registry.

Relationship to patient

For related donors, indicate the biological relationship of the donor to the recipient by selecting one of the options from the list:

Syngeneic (monozygotic twin) - the donor is a twin who developed from the same zygote as the patient and thus shares the same histocompatibility genes. This option can only be selected for matched, related donors.

Sibling - a brother or a sister of the patient including a non-monozygotic twin.

For other relatives, select **Other related** and specify the relationship type by checking one of the options from the list. If the relationship type is not available in the list, check the **Other** box and specify the type in the textbox in English.

Related donor

If the donor has a blood relation with the patient, provide the data below.

*Both haplotypes confirmed by family studies?

Genotypic HLA identity should be confirmed by family studies (Family study is that both parents and child/children should all have been HLA typed so that the involved haplotypes can be clearly identified) for all six HLA loci (to exclude recombination) wherever possible. In other words, if the patient's haplotypes have been confirmed for their family donors to ensure the patient shares the whole haplotype

with the family donor. For both matched and mismatched related donors, select **No**, if no confirmation was done, otherwise select **Yes**. If it is unknown whether both haplotypes were confirmed by family studies, select **Unknown**.

*HLA match type

Report whether the HLA matched or not between the related donor and the patient. If both haplotypes matched (12/12), select **Match**. Otherwise, select **Mismatch**.

Note: the definition of a match is that all 6 loci (A, B, C, DRB1, DQB1 **and** DPB1) of patient and donor are identical.

*Method used for patient/donor HLA typing

HLA typing can be done through 2 different methods: **molecular** or **serology**. Nowadays, the molecular method is almost always used. The molecular method provides results in higher resolution - at least 4 digits (eg. A*01:01) - whereas the serology method only provides results in a lower resolution (2 digits, eg. A*01). Please indicate which method was used (select all that apply).

*Number of mismatches, allelic

When molecular typing was done (high resolution, at least 4 digits), indicate for each locus the number of mismatches (**0**, **1** or **2**) or if the locus was **Not evaluated**.

*Number of mismatches, antigenic

When serological typing was done (low resolution, 2 digits), indicate for each locus the number of mismatches (**0**, **1** or **2**) or if the locus was **Not evaluated**.

Note: An antigenic difference (serology method, 2 digits) implies an allelic difference (molecular method, at least 4 digits), so the number of allele differences can never be lower than the number of antigen differences.

Unrelated donor

If the donor has no blood relation with the patient, provide the data below.

*Method used for patient/donor HLA typing

HLA typing can be done through 2 different methods: **molecular** or **serology**. Nowadays, the molecular method is almost always used. The molecular method provides results in higher resolution - at least 4 digits (eg. A*01:01) - whereas the serology method only provides results in a lower resolution (2 digits, eg. A*01). Please indicate which method was used (select all that apply).

*Number of mismatches, allelic

When molecular typing was done (high resolution, at least 4 digits), indicate for each locus the number of mismatches (**0**, **1** or **2**) or if the locus was **Not evaluated**.

*Number of mismatches, antigenic

When serological typing was done (low resolution, 2 digits), indicate for each locus the number of mismatches (**0**, **1** or **2**) or if the locus was **Not evaluated**.

Note: An antigenic difference (serology method, 2 digits) implies an allelic difference (molecular method, at least 4 digits), so the number of allele differences can never be lower than the number of antigen differences.

IMPORTANT NOTE:

LABORATORY RESULTS WITH HLA TYPING must be added to the database for all the donors.

Check the manual on HLA data entry in the manuals and reference documents section for more details.

Additional Assessments

Are there Donor-Specific Antibodies (DSA) against HLA?

The presence of donor-specific anti-HLA antibodies (DSA) is associated with a higher risk of Graft Failure in the context of haploidentical cord blood and unrelated donor transplants, and it may in fact translate into a reduced overall survival.

Indicate if clinically significant donor-specific anti-HLA antibodies were detected by selecting **No** or **Yes**. Select **Unknown**, if it is not known whether the antibodies were detected. Select **Not evaluated** if testing for clinically significant donor-specific antibodies was not performed.

HLA loci the DSA are directed against

If you answered **Yes** to the previous question, also specify the HLA locus against which the antibodies are directed.

Did the patient have desensibilisation therapy?

If you answered **Yes** to the question *Are there Donor-Specific Antibodies (DSA) against HLA?* and the patient's diagnosis was registered using the 'Haemoglobinopathies' form, also indicate if the patient had desensibilisation therapy by selecting **No** or **Yes**. If answered **Yes**, also specify the type of therapy.

Are the DSA red cell antibodies?

If you answered **Yes** to the question *Are there Donor-Specific Antibodies (DSA) against HLA?* and the patient's diagnosis was registered using the 'Haemoglobinopathies' form, also indicate whether the antibodies are directed against red blood cells by selecting No or Yes.

Are they cross-reacting with the red cells of the donor?

If you answered **Yes** to the previous question, indicate whether the antibodies cross-react with the red cells of the donor by selecting **No** or **Yes**.

Preparative Regimen

Preparative (conditioning) regimen given?

Conditioning is the preparative regimen that is administered to patients undergoing HCT before the infusion of stem cell grafts. The pretransplant conditioning may consist of TBI and/or chemotherapy. However, there are instances when a preparative regimen may not be given: for example, for Primary Immunodeficiency Disorders.

In some cases, especially in patients with MDS and blasts in the bone marrow, or in patients with refractory or non-complete remission prior to an allograft, it is becoming increasingly common to use AML-like therapy followed immediately (usually after 3 days) by mainly reduced conditioning regimen (e.g. FLAMSA regimen). In such cases, the AML-like therapy should be reported as part of the preparative regimen (conditioning).

If a preparative regimen was given select **Yes**, otherwise select **No**.

NOTE: Fill in this section if the patient is still alive but has not received HCT due to health reasons, regardless of whether the conditioning was complete or not.

Drugs given?

Indicate if the preparative regimen consisted of drug treatment (any active agent, including chemotherapy, monoclonal antibody, polyclonal antibody, serotherapy, etc.) by selecting **Yes** or **No.** If answered **Yes**, specify the treatment in *Specification and dose of the preparative regimen)*.

What type of conditioning regimen was used?

Indicate the type of the conditioning regimen by selecting one of the following:

Myeloablative conditioning (MAC) - the conventional preparative regimen that consists in ablation of the marrow with pancytopenia which can last for over a month, require CT for marrow recovery, and results in complete donor chimaerism.

Examples of standard intensity conditioning regimens for adults and older children. (Dosages have to be adapted for young children)

- Busulfan 16 mg/kg po / 3.2 mg/kg iv + cyclophosphamide 120-200 mg/kg
- Cyclophosphamide 120 mg/kg fractionated, TBI 12 Gy (fractionated) ± Anti-Thymocyte Globulin
- TBI 10-14 Gy; Busulfan 16 mg/kg po/ 3.2 mg/kg iv; ± other agent
- 200 mg/m² Melphalan

Example of a sequential conditioning regimen in table 3:

	D-15	D-14	D-13	D-12	D-11	D-10	D-9	D-8	D-7	D-6	D-5	D-4	D-3	D-2	D-1	D0
Cytarabine	2 x 1000 mg/m2	2 x 1000 mg/m2	2 x 1000 mg/m2	2 x 1000 mg/m2												
Fludarabine	30 mg/m2	30 mg/m2	30 mg/m2	30 mg/m2												
Amsacrine	100 mg/m2	100 mg/m2	100 mg/m2	100 mg/m2												
Anti-Thymocyte Globulin												0.5 mg/kg	2.5 mg/kg	3 mg/kg		
Busulfan								4 x 0.8 mg/kg	4 x 0.8 mg/kg	4 x 0.8 mg/kg	4 x 0.8 mg/kg					

Table 3. Example of a sequential conditioning regimen[1]

Reduced intensity conditioning (RIC) uses lower, less toxic doses of chemotherapy and radiation than the conditioning regimen that is given before standard allogeneic Transplantations. These regimens are used for certain patients who are older, who have organ complications or who are otherwise not healthy or strong enough to undergo standard allogeneic transplantation.

There are many different reduced-intensity conditioning protocols and the intensity of the chemo-radiotherapy can vary from levels very close to conventional conditioning to regimens based only on immunosuppression. However, not all reduced-intensity protocols are non-myeloablative. The following guidelines should be followed to determine whether a regimen is truly non-myeloablative:

Any regimen with 50% or less equivalence to a standard conditioning regimen is considered non-myeloablative. This includes not only the 50% reduction of the total dose of a given drug (or TBI) but

[1] The following sequence is a borderline case, but considered by the Definitions Committee to be Standard (myeloablative) conditioning.

also the use of a single drug in a standard dose but without other drugs (or TBI) usually included in the standard protocol.

The standard conditioning regimens vary according to the disease, so the non-myeloablative regimens will also vary. **The addition of ATG or any mono or polyclonal antilymphocyte antibody or the addition of purine analogues does not change the intensity category.**

The above definition can be applied also to published protocols not included in the examples below.

Examples of reduced intensity conditioning regimens[2]

- Cyclophosphamide 1200 mg/m2 ± Anti-Thymocyte Globulin
- Cyclophosphamide ≤ 60 mg/kg ± TBI ≤ 6 Gy (fractionated) ± purine analogue ± Anti-Thymocyte Globulin
- Melphalan ≤ 100 mg/m² ± purine analogue ± Anti-Thymocyte Globulin
- Melphalan 70-140 mg/m2 ± purine analogue ± Alemtuzumab
- Busulfan ≤ 8 mg/kg po / 1.6 mg/kg iv ± TBI ≤ 6 Gy (fractionated) ± purine analogue ± Anti-Thymocyte Globulin

Specification and dose of the preparative regimen

Select all the agents (chemotherapy, antibodies, hormones, etc.) received by the patient as a part of the preparative regimen. They must all have been given before the actual date of cell infusion (HCT date or Day 0). If collecting data retrospectively or if drugs were stopped due to adverse events or early death, please, still register the drugs which were given. With respect to antibodies, only indicate the ones infused directly into the patient before administration of the graft and not those used ex vivo for graft manipulation. Any drugs, antibodies, etc. administered after the transplantation should not be entered here.

If the drug/agent is not available on the list, select **Other** and report the generic drug/agent name(s) in the textbox in English.

Please consult the **LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS** on the EBMT website for drug/agent names. This document provides alternative names for many drugs/agents. Once you have found the drug/agent of interest on the list, add its database name to the table. Please specify dosages and units only for individual drugs and not for regimens.

[2] Only regimens with dosages equal to or below these limits should be classified as non-myeloablative.

In addition, indicate the administered cumulative dose as specified in the treatment protocol. Multiply the daily dose in mg/kg or mg/m^2 by the number of days (e.g. for Busulfan given 4 mg/kg daily for 4 days, the total dose to report is 16 mg/kg.) Report the dose units as either **mg/m2** or **mg/kg** for non-radioactive agents and as either **mCi** or **MBq** for radioactive ones. If the dose is reported in a unit other than those listed, convert the dose to the appropriate unit.

Please pay attention to the fact that :

- Anti-Thymocyte Globulin and Anti-Lymphocyte Globulin must be reported in the section GvHD prevention, although administration started during the preparative (conditioning) regimen.

- Cyclophosphamide :

* If Cyclophosphamide was administered before the allogeneic transplantation, it must be reported in the Preparative (conditioning) regime section.

* If Cyclophosphamide was administered after the allogeneic transplantation, it must be reported in the GvHD prevention section.

* If Cyclophosphamide was administered before and after the allogeneic transplantation, it must be reported in both sections: the Preparative (conditioning) regime section and the GvHD prevention section.

Busulfan

Route of administration

If the patient received busulfan as part of the preparative regimen, indicate the route of administration by selecting one of the options from the list.

Drug monitoring performed

If the patient received busulfan as part of the preparative regimen, indicate if AUC-based drug monitoring was performed by selecting **No** or **Yes**. Busulfan drug monitoring is done during the conditioning treatment with the aim to adjust the dose.

Total AUC

If you answered **Yes** to the previous question, specify the total AUC value. AUC means area under the curve and is a common way of assessing drug levels.

AUC unit

Report the total AUC units as either **mg x hr/L** or **micromol x min/L** or **mg x min/mL**. If the total AUC is reported in a unit other than those listed, convert it to the appropriate unit.

Carboplatin

Drug monitoring performed

If the patient received carboplatin as part of the preparative regimen, indicate if AUC-based drug monitoring was performed by selecting **No** or **Yes**.

Total AUC

If you answered **Yes** to the previous question, specify the total AUC value.

AUC unit

Report the total AUC units as either **mg x hr/L** or **micromol x min/L** or **mg x min/mL**. If the total AUC is reported in a unit other than those listed, convert it to the appropriate unit.

Total body irradiation (TBI)

Indicate if the patient underwent total body irradiation as part of the preparative treatment. If the answer is **Yes**, specify also:

Total prescribed radiation dose as per protocol

If the patient received total body irradiation as part of the preparative treatment, report the total prescribed dose in Gy.

Number of fractions

If the patient received total body irradiation as part of the preparative treatment, report the number of fractions.

Number of radiation days

If the patient received total body irradiation as part of the preparative treatment, report the number of radiation days.

Total lymphatic irradiation (TLI)

Indicate if the patient underwent total lymphatic irradiation as part of the preparative treatment. If the answer is **Yes**, specify also:

Total prescribed radiation dose as per protocol

If the patient received total lymphatic irradiation as part of the preparative treatment, report the total prescribed dose in Gy.

Number of fractions

If the patient received total lymphatic irradiation as part of the preparative treatment, report the number of fractions.

Number of radiation days

If the patient received total lymphatic irradiation as part of the preparative treatment, report the number of radiation days.

Total abdominal irradiation (TAI)

Indicate if the patient underwent total abdominal irradiation as part of the preparative treatment. If the answer is **Yes**, specify also:

Total prescribed radiation dose as per protocol

If the patient received total abdominal irradiation as part of the preparative treatment, report the total prescribed dose in Gy.

Number of fractions

If the patient received total abdominal irradiation as part of the preparative treatment, report the number of fractions.

Number of radiation days

If the patient received total abdominal irradiation as part of the preparative treatment, report the number of radiation days.

GvHD preventive treatment

This is an immunosuppressive treatment that is given to the patient in a prophylactic manner to prevent the development of GvHD. If collecting data retrospectively, please specify the drugs which were intended to be given.

Patients receiving syngeneic transplants do not receive this treatment.

GvHD preventive treatment

Indicate if GVHD prophylaxis was given by selecting **No** or **Yes**. If you answered **Yes**, specify the type of treatment given by selecting one of the options:

Drugs - Select all the agents (chemotherapy, antibodies, hormones, etc.) received by the patient as a part of the immunosuppressive treatment.

Most of the time, the immunosuppressive treatment includes cyclosporine and methotrexate. Cyclosporine may also be given alone. More recently, newer agents are being used for the prevention of GvHD: tacrolimus, mycophenolate mofetil, and monoclonal antibodies such as alemtuzumab (Campath). If the patient was given "Campath in the bag", report it here.

If the drug/agent is not available on the list, select **Other** and report the generic drug/agent name(s) in the textbox in English.

Please consult the **LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS** on the EBMT website for drug/agent names. This document provides alternative names for many drugs/agents. Once you have found the drug/agent of interest on the list, add its database name to the table.

Anti-Thymocyte Globulin|Anti-Lymphocyte Globulin
Product name

If the patient received anti-thymocyte globulin or anti-lymphocyte globulin as part of the GvHD prophylaxis or preventive treatment, report the product name.

Origin

If the patient received anti-thymocyte globulin or anti-lymphocyte globulin as part of the GvHD prophylaxis or preventive treatment, report the origin of the globulin by selecting one of the options from the list. If the origin is other than rabbit or horse, select **Other** and report the origin in the textbox in English.

Anti-Thymocyte Globulin (ATG) total cumulative dose (mg/kg)

Indicate the administered cumulative dose of ATG as specified in the treatment protocol. Multiply the daily dose in mg/kg by the number of days. Report the dose units as **mg/kg**. If the dose is reported in a unit, convert the dose to the appropriate unit.

Cyclophosphamide
Post Transplant Cyclophosphamide (PTCY) cumulative dose (mg/kg)

Indicate the administered cumulative dose of PTCY as specified in the treatment protocol. Multiply the daily dose in mg/kg by the number of days. Report the dose units as mg/kg. If the dose is reported in a unit, convert the dose to the appropriate unit.

Post Transplant Cyclophosphamide (PTCY) timing schedule

Indicate whether the post transplant Cyclophosphamide was given as a single dose on day 3, a single dose on day 5, doses on days 3 and 4 or doses on days 3 and 5. If another timing schedule was used, please indicate this by using the Other and specifying in the textbox in English the specifics.

Bibliography

1. Optimising 'search, match & connect' [Internet]. WMDA. 2017 [cited 2023 Jul 3]. Available from: https://wmda.info/optimising-search-match-connect/
2. ISBT 128 [Internet]. ICCBBA. [cited 2023 Jul 3]. Available from: https://www.iccbba.org/about-iccbba