EBMT Registry

Autologous HCT

Day 0

Guide to the completion v2.3 of the EBMT data collection form:

AutoHCT_Day0_Core_Extended_v2.3

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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.

Autologous HCT Day 0

Autologous HCT is a treatment where patients receive their own stem cells to replace diseased or damaged bone marrow.

Day 0 is considered the day of the first haematopoietic 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 an autologous HCT. No data items should be left blank unless specifically stated in the definition.

Date of this HCT

Report the date of the first stem cell infusion if there are multiple infusions over several days after the same conditioning regimen. If a patient died before infusion, the planned date of the first infusion shall be reported.

Centre where treatment took place

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

Patient UPN for this treatment

Report the patient UPN (hospital unique patient number).

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 autologous HCT

Indicate the chronological number of the current autologous HCT among other autologous HCTs that this patient has received throughout his/her lifetime, regardless of whether the previous autologous HCT has been performed in your centre or in other centres. It is NOT the serial number of this autologous HCT within all the autologous 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 5 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 autologous 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 (eg. as part of a planned multiple graft program).

Relapse/progression after previous treatment (HCT/CT/IST/GT) - 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/IST/GT) - 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/IST/GT treatment before this autologous HCT.

Type of the last main treatment before this one

Select the type of the previous HCT/CT/IST/GT treatment before this autologous HCT.

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/IST/GT treatment was performed in another institution than the one performing this autologous 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.

Graft information

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 tandem autologous transplants for PCN. In the case of tandem transplants, both Status at HCT_CT_IST and HCT_D0 Forms will be completed for each of the transplants (4 forms in total) but they will be followed up as if it was a single treatment. Therefore, Day 100 and the subsequent annual/unscheduled follow-ups will start counting on the second transplant date.

Some patients may have received a transplant 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 autologous HCT as a part of a (planned) multiple (sequential) graft program/protocol. Please also enter **Yes** when the current autologous HCT was part of a planned

multiple graft program even in those cases where the 2nd HCT did not take please (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 autologous HCT in the program.

Source of stem cells

Select all sources of stem cells that were used for this autologous HCT. It can be: bone marrow, peripheral blood, cord blood. If the source of stem cells for this autologous HCT is not available in the list, select the **Other** checkbox and report the source in the textbox in English.

Graft manipulation ex-vivo

Indicate if ex-vivo graft manipulation was performed on the cells that were infused for this autologous HCT. Gene therapy, red blood cell removal or volume reduction should not be reported here. *If the answer is **Yes**, report also*:

CD34+ enrichment

Check this box if ex-vivo graft manipulation was performed on CD34+ cells that were infused in this autologous HCT.

Other manipulation

Select this box if the ex-vivo graft manipulation was not on CD34+ cells and specify the manipulation that was performed in the textbox in English (i.e. T-cell depletion)

Was the graft cryopreserved prior to infusion?

Indicate whether the graft was cryopreserved before infusion or not.

Mobilisation (Autoimmune Diseases only)

This section only needs to be completed for patients that underwent autologous HCT for an autoimmune disease.

Mobilisation drugs given?

Indicate if the patient received mobilisation drugs prior to apheresis for the autologous HCT. *If the answer is **Yes**, indicate also:*

Start date of mobilisation

Report the start date of the mobilisation if the patient received mobilisation therapy.

Cyclophosphamide

Indicate if the patient received cyclophosphamide as a mobilisation drug.

*If the answer is **Yes**, indicate also:*

Cyclophosphamide dose (g/m^2)

If the patient received cyclophosphamide as a mobilisation drug, report the total dose in grams per square metre.

Corticosteroids

Indicate if the patient received any corticosteroids as a mobilisation drug.

*If the answer is **Yes**, indicate also:*

Corticosteroids daily dose (mg/kg)

If the patient received any corticosteroids as a mobilisation drug, report the daily dose the patient received in milligrams per kilogram.

G-CSF

Indicate if the patient received growth colony stimulating factors as a mobilisation drug.

Plerixafor

Indicate if the patient received plerixafor as a mobilisation drug.

Other mobilisation drug

Select this box if the patient received any mobilisation drug other than listed above (not cyclophosphamide, corticosteroids, G-CSF or plerixafor), report the generic name of the drug in English in the textbox.

Consult the LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS on the EBMT website for drugs/regimens names.

Extended dataset

Mobilisation
(All diagnoses except Autoimmune Diseases)

Indicate if the patient received mobilisation drugs prior to apheresis for the autologous HCT. Select **Unknow**n if this information is unavailable.

Start date of mobilisation

Report the start date of the mobilisation. If the date is not available, mark **Date unknown**.

Drugs given at mobilisation

Indicate which drugs the patient received for mobilisation (cyclophosphamide, corticosteroids, G-CSF, plerixafor or other). Report the generic name of the drug in English in the textbox.

Consult the LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS on the EBMT website for drugs/regimens names.

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 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’. For autograft it is necessary to cryopreserve the collected stem cells until the time when the patient will be submitted to the autograft (this may be weeks, months, rarely years after the collection). 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.

Indicate the source of the cell product and then report for each source of product 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 (x105/kg, x106/kg, x107/kg or x108/kg).

Preparative regimen (All Diagnoses)

Indicate if the patient received a preparative regimen. Any lymphodepleting treatment is considered a preparative regimen; include chemotherapy, monoclonal antibodies, polyclonal antibodies and serotherapy.

Preparative (conditioning) regimen given?

If the patient received a preparative regimen, report the treatments in Specification and dose of the preparative regimen.

Serotherapy given (ATG, ALG, alemtuzumab) (for Autoimmune Diseases only)

This question only needs to be answered for patients who underwent this autologous HCT for an autoimmune disease. *If the patient received any serotherapy (ATG, ALG, alemtuzumab), report the treatments in Specification and dose of the preparative regimen.*

Specification and dose of the preparative regimen

Check the box next to the name of the drug/chemotherapy, indicate the total prescribed cumulative dose of each drug as per protocol, specify the units of the dose (e.g. mg/m^2 or mg/kg, mCi or MBq).

In order to calculate the total prescribed cumulative dose, multiply 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, total dose to report is 16mg/kg.

Check all chemotherapy/drugs that the patient received as part of the preparative regimen.

Please consult the LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS on the EBMT website for drugs/regimens names to avoid reporting them under different names. Please specify dosages and units only for individual drugs and not for regimens.

Anti-Thymocyte Globulin or Anti-Lymphocyte Globulin

Product name

If the patient received anti-thymocyte globulin or anti-lymphocyte globulin as part of the preparative regimen, report the product name.

Origin

If the patient received anti-thymocyte globulin or anti-lymphocyte globulin as part of the preparative regimen, report the origin of the globulin (rabbit, horse or other origin). In case of **Other** than rabbit or horse origin, report the origin of the globulin in the textbox in English.

Busulfan

Route of administration

If the patient received busulfan as part of the preparative regimen, indicate the route of administration (oral, IV or both).

Drug monitoring performed

If the patient received busulfan as part of the preparative regimen, indicate if drug monitoring was performed. Busulfan drug monitoring is done during the conditioning treatment with the aim to adjust the dose.

Total AUC

If the patient received busulfan as part of the preparative regimen and drug monitoring was performed, report the area under the curve (AUC). AUC is a common way of assessing drug levels.

AUC unit

Select the unit that the area under the curve was measured in.

Carboplatin

Drug monitoring performed

If the patient received carboplatin as part of the preparative regimen, indicate if drug monitoring was performed.

Total AUC

If the patient received carboplatin as part of the preparative regimen and drug monitoring was performed, report the area under the curve.

AUC unit

Select the unit that the area under the curve was measured in.

Other chemotherapy

If the patient received any other drug as part of the preparative regimen than the ones listed, consult the list of chemotherapy drugs and regimens to find the drug. If the drug is not available, report the generic name of the drug in the textbox in English.

Total body irradiation

Indicate if the patient received 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

The radiation treatment can be given in one single dose or in different divided doses (this last one is fractionated radiation). If the patient received total body irradiation as part of the preparative treatment, report the number of fractions in which it was administered.

Number of radiation days

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