

# Autologous HCT

## Day 0

**Guide to the completion of the EBMT data collection form: AutoHCT\_Day 0\_v1.0**

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**EBMT Registry**

EBMT Clinical Research & Registry Department



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## Autologous HCT

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.

### 1. Date of this HCT: *(or planned date of HCT if patient died before treatment)*

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.

### 2. 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.

### 3. Survival status at HCT:

Report if the patient's survival status at the (planned) date of HCT was **Alive**. If the conditioning regimen was started, but the patient died before infusion, select **Died after conditioning but before HCT**.

### 4. Indication diagnosis for this HCT:

Select the diagnosis that was the indication for this HCT.

### 5. Chronological number of this treatment:

Report the chronological number of this HCT, counting all HCTs and cellular therapies for this patient in total.

### 6. Chronological number of this HCT:

Report the chronological number of this HCT, counting both previous autologous and allogeneic HCTs for this patient in total.

## 7. Chronological number of this autologous HCT

Report the chronological number of this autologous HCT, counting all previous autologous HCTs for this patient in total.

## 8. Complete this section only if the chronological number of the treatment is >1 for this patient:

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

### 8.1. Reason for this HCT:

If this is not the first treatment for this patient, select the reason the patient required a subsequent HCT. It can be:

- **Indication diagnosis**
- **Relapse/progression after previous treatment (HCT/CT)**
- **Complication after previous treatment (HCT/CT)**
- **Primary graft failure**
- **Secondary graft failure**
- **Secondary malignancy**

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

### 8.2. Date of the last treatment before this one:

Report the date of the previous treatment (HCT/CT) before this autologous HCT.

### 8.3. Type of the last treatment before this one:

Select the type of the previous treatment before this autologous HCT.

It can be: autologous HCT, allogeneic HCT, cellular therapy, immunosuppressive treatment.

#### 8.4. Was the last treatment performed at another institution?

Indicate if the previous treatment was performed in another institution than the one performing this autologous HCT.

*If the answer is **Yes** report also 8.4.1 -8.4.3:*

##### 8.4.1. CIC (if known):

Report the CIC of the centre performing the previous HCT/CT if this is known.

##### 8.4.2. Name of institution:

Report the name of the centre performing the previous HCT/CT.

##### 8.4.3. City:

Report the city the centre performing the previous HCT is located in.

#### 9. Is this HCT part of a multiple (sequential) graft program/protocol?

Indicate if this autologous HCT is part of a multiple graft program.

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

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

Report the number of this autologous HCT in the multiple graft program.

#### 10. 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.

#### 11. 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:*

### 11.1. CD34+ manipulation

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

### 11.2. 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)

## 12. Mobilisation

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

### 12.1. Mobilisation drugs given?

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

#### 12.1.1. Start date of mobilisation

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

#### 12.1.2. Cyclophosphamide

Indicate if the patient received cyclophosphamide as a mobilisation drug.

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

##### 12.1.2.1. Cyclophosphamide dose

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

#### 12.1.3. Corticosteroids

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

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

##### 12.1.3.1. Corticosteroids daily dose

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

#### 12.1.4. G-CSF

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

#### 12.1.5. Plerixafor

Indicate if the patient received plerixafor as a mobilisation drug (number of doses of plerixafor are not asked for?)

#### 12.1.6. 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.*

### 13. Preparative (conditioning) regimen given

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

*If the patient received a preparative regimen, report the treatments in section 15.*

### 14. Serotherapy given (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 section 15.*

### 15. 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<sup>2</sup> or mg/kg, mCi or MBq).

In order to calculate the total prescribed cumulative dose, multiply daily dose in mg/kg or mg/m<sup>2</sup> 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.

### 15.1. For Anti-Thymocyte Globulin or Anti-Lymphocyte Globulin

#### 15.1.1. Product name

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

#### 15.1.2. 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.

### 15.2. For Busulfan

#### 15.2.1. Route of administration

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

#### 15.2.2. Drug monitoring performed

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

#### 15.2.3. 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).

#### 15.2.4. AUC unit

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

### 15.3. For Carboplatin

#### 15.3.1. Drug monitoring performed

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

### 15.3.2. Total AUC

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

### 15.3.3. AUC unit

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

## 15.4. 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.

## 16. Total body irradiation

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

### 16.1. 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.

### 16.2. 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.

### 16.3. Number of radiation days

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