EBMT Registry

Patient Registration

Guide to the completion of the EBMT data collection form:

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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.

Patient Registration

Informed Consent

Did the patient consent to having their data submitted to EBMT?

Answer **Yes** if the patient or their legal guardian have signed the informed consent form and consent patient's data being reported to and processed by the EBMT Registry. Answer **No** if the written consent was not received or given.

If the answer to this question is **No**, only minimal essential data can be entered into the EBMT Registry as an anonymous event.

First informed consent date

Indicate the date the first informed consent was given (with signed informed consent form) by the patient or their legal guardian to having their data submitted to EBMT.

EBMT collects patient pseudonymised data under patient consent lawful basis, the first day of consent is collected and cannot be modified in the system by the users, because the first consent date is the date when the relation patient-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.

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

In the scenario that a patient has been transferred from another hospital where consent was already collected, the new centre is responsible for obtaining the patient's consent (its date shall be recorded in the data field ***Most recent informed consent date***) and providing evidence of the consent acceptance following GDPR and their local regulations. The first date of consent from the previous hospital will be maintained since it is when the patient-EBMT relation was authorised.

Note: once this date is added to the EBMT Registry, this field can not be edited. Please contact EBMT Registry Helpdesk if it is required to correct this data field, specifying all the details and the reason for such change.

Most recent informed consent date

Indicate the date the latest informed consent form was signed by the patient or their legal guardian.

In the EBMT Registry initially this field is pre-populated with the date entered into the ***First informed consent date*** and it shall be edited/updated by the centre in case the patient or their legal guardian signed an informed consent form different from the form registered in the first informed consent field above.

Note: this date shall be edited in the EBMT Registry whenever the patient or their legal guardian signs a new informed consent form. The remaining questions of this section below should always reflect the patient details as per the most recent informed consent form signed.

Is your centre using the EBMT consent form?

Answer **Yes** if your centre is using the EBMT Patient Consent form published at the EBMT website (see Informed Consent Form Templates | EBMT).

Answer **No** if your centre is using any other than published at EBMT website consent form, this includes your own Informed Consent even upon agreement with EBMT.

Since EBMT is collecting data about patients that speak different languages, the EBMT Patient Consent Form was translated into a number of languages and published together with translation certificates. Any other than published at EBMT website translated versions of the consent form are considered as unofficial and should not be referred to as EBMT Patient Consent form.

Did the patient consent to data sharing with health authorities and/or researchers?

Indicate whether the patient or their legal guardian consent to patient's personal data in the EBMT Registry being shared with health authorities and researchers across scientific or clinical institutions, provided that an adequate level of protection for patient's privacy is applied or that sufficient contractual safeguards are arranged if this data is to be sent outside the European Economic Area.

If the answer is **No** the data will not be used in joint studies of EBMT working parties with health authorities (unless there is a legal obligation) and/or other researchers or clinical institutions.

Did the patient consent to data sharing with HTA bodies/reimbursement agencies?

Indicate whether the patient or their legal guardians consent to having patient's pseudonymized data being shared with Health Technology Assessment bodies (HTA) and/or reimbursement agencies.

HTA bodies are public organisations that provide recommendations on medicines and other healthcare interventions that can be paid for or reimbursed. HTA organisations look at the relative effectiveness and cost effectiveness of medicines that have been authorised.

If the answer is **No** the data will not be used in joint studies of EBMT working parties with HTA bodies.

Did the patient consent to data sharing with Market Authorisation Holders (MAH)?

Indicate whether the patient or their legal guardians consent to patient's pseudonymised data in the EBMT Registry being shared with the Marketing Authorisation Holder (MAH) of the IEC therapy the patient receives to facilitate the post authorisation obligations the MAH has to the EMA, national health authorities and HTA bodies/reimbursement agencies, provided that an adequate level of protection for the patient privacy is applied or that sufficient contractual safeguards are arranged if patient's pseudonymised data is being shared with MAHs that are situated outside the European Economic Area.

If the answer is **No** the data will not be used in joint studies of EBMT working parties with MAH.

Did the patient consent to their medical records being reviewed?

Indicate whether the patient or their legal guardians gave permission to monitors and auditors from the EBMT and regulatory authorities to review the patient's medical records in accordance with applicable laws.

If the answer is **No** the authorised monitors will not be allowed to access the patient's data during their audit activities.

Patient Data

Hospital Unique Patient Number or code (UPN)

Enter here the unique number of the patient within the centre that is registering this patient in EBMT Registry.

Patient number/code is used by the treating centre to uniquely identify this patient. This item is compulsory. It must be unique in the centre, and should be sufficient to identify the patient within the hospital environment. The number should not be liable to change. If a patient receives a second treatment, no new number should be assigned: the same unique number for this patient should be used when registering subsequent cell infusions and/or HCTs.

If the patient receives treatments in different centres, each centre shall give the patient their own unique UPN. It is to be noted in the header of each paper version of the EBMT data collection form.

Date of birth

The year of birth is a compulsory field, while month and date fields are strongly recommended to be entered.

Note: the date of birth is an important information used to avoid patient duplication and accurate calculation of the patient age at different events in the patient timeline. Failure to provide the full date of birth (with year, month and date) due to legal, ethical or any other reason will result in increasing the chances of patient duplication in the system.

Sex (at birth)

Indicate if patient sex at birth is **Male** or **Female** by ticking the correspondent check box.

Initials

Enter only one letter as the initial of the first name of the patient followed by one letter as the initial of the surname of the patient (e.g.: Madhu Gupta should be written as M/G, John Peters should be written as J/P).

In case of complex or multiple names or surnames, the patient's preference should be always asked to identify two letters indicating the initials (e.g.: Sarah DiAmico may choose to have S/D or S/A based on patient preference, Maria Silvia Jose Mata should be written as M/J if the patient prefers Maria as the first name and Jose as the surname).

Note: correct and consistent indication of initials is extremely important in order to avoid patient duplication in the database, it ensures the record can be traced even if the patient remains anonymous.

Blood group

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

Note: in some cases patient blood group may change after transplant, please enter here the patient blood group pre-transplant. Do not edit the field if the patient blood group changed after the treatment.

Rhesus factor

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

Note: in some cases patient rhesus factor may change after transplant, please enter here the patient rhesus factor pre-transplant. Do not edit the field if the patient rhesus factor changed after the treatment.

Participation in non-EBMT national/international study/trial

Check patient records and consult your physician to answer this question.

Answer **No** if the patient is not taking part in any national or international prospective study or trial.

Answer **Yes**, if the patient has been included into any prospective study or trial,

EBMT working party studies shall not be considered while answering this question.

Name/identifier of study/trial

If answered Yes to a previous question, specify here identifier or name of the study/trial the patient is part of.

Can the patient be included in EBMT studies?

If answered Yes to a previous question, specify if the patient can be included into EBMT retrospective studies.

Answer **Yes** if the patient can be included into EBMT studies.

Answer **No** if the patient shall not be included into EBMT studies (e.g. due to confounding or effect modifications).

Note: the answer reflects the current position on possibility of the patient’s inclusion into EBMT studies. This item can be changed or updated in case any changes appear.

Appendix (for relevant centres only)

Due to legislation requirements some centres also have to specify the questions marked as attachment to the Patient registration form. If not required by the country legislation, the questions of this section are optional and should be left blank.

Area or postal code where patient was living during the last graft therapy

Enter the postal or area code where the patient lived while having the last graft therapy.

This information is collected at patient registration and is kept as part of the patient details in EBMT Registry. When changes arise, data entry manager should edit patient details and update/change this field in the EBMT Registry online application.

Ethnicity

If required by local regulation/legislation, check the box that best describes ethnicity of the patient, otherwise answer **Not stated** or **Unknown** whatever answer best corresponds.

Chose ethnicity from the following answer options:

- White - British
- White - Irish
- White - Any other White background
- Mixed - White and Black Caribbean
- Mixed - White and Black African
- Mixed - White and Asian
- Mixed - Any other mixed background
- Asian or Asian British - Indian
- Asian or Asian British - Pakistani
- Asian or Asian British - Bangladeshi
- Asian or Asian British - Any other Asian background
- Black or Black British - Caribbean
- Black or Black British - African
- Black or Black British - Any other Black background
- Other Ethnic Groups - Chinese
- Other Ethnic Groups - Any other ethnic group