# Patient Information Leaflet for the EBMT Registry

Dear Madam/Sir,

You have been given this leaflet because you are receiving a blood or bone marrow transplantation, immune effector cell therapy and/or immunosuppressive treatment. We would like to invite you to share your data with the Registry (database) of the European Society for Blood and Marrow Transplantation (EBMT).

The EBMT is a not-for-profit organisation that consists of hospitals and professionals working in the field of clinical bone marrow transplantation and immune effector cell therapy. The EBMT maintains an international patient database known as the EBMT Registry. The Registry contains patients’ clinical data that is used in scientific research and assessments of the safety and efficacy of the treatments you receive. The goal of the Registry is to save the lives of patients with blood cancers and other life-threatening diseases.

In this leaflet, we would like to explain why we are asking you to share your data with the EBMT Registry; what the purpose of data processing is; which data is being collected; how your data is being protected and what your rights are. You are free to decide whether or not to share your data with the EBMT Registry. Please read this information leaflet carefully and discuss it with your partner, family or friends. Take as much time as you need to think about sharing your data.

If, after reading the information, you agree to take part, you will be asked to sign and date two copies of the consent form. You will be given one copy to keep and the other copy will remain in your patient file at the hospital. If you decide not to share your data or to withdraw at a later date, this will not affect the type or quality of treatment you receive. Please ask your treating physician if anything is not clear or if you would like some more information.

If you are giving consent on behalf of a child in your care, please explain to the child as much as they can understand.

# Summary

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| Registry of the European Society for Blood and Marrow Transplantation (EBMT) |
| Aim of the RegistryThe main function of the Registry is to collect clinical data for research and to enhance the safety and effectiveness of treatments and the quality of care. The ultimate goal is to save the lives of patients with blood cancers and other life-threatening diseases.  |
| Who is invited to share data with the EBMT?Patients receiving blood or bone marrow transplantation, immune effector cell therapy and/or immunosuppressive treatment are invited to share their data.  |
| What will happen if you agree to share your data with the EBMT? If you decide to share your data, data on your disease, treatment and response to treatment will be collected from your routine clinic visits. You will not be required to visit the hospital specifically for this purpose.  |
| What will happen to your personal data?All your data will remain confidential and will be stored in a certified and secure database of the European Society for Blood and Marrow Transplantation (EBMT). All data processing activities will comply with the European General Data Protection Regulation (2016/679) and applicable local laws. |
| Who should you contact in case you have questions? |
| *At your institute:*Name:Position/Title: Address:Phone number: | *At the EBMT:*EBMT Data Protection OfficerE-mail: data.protection@ebmt.org  |

# Why are you being invited to share your data with the Registry?

You are being invited to share your data with the EBMT Registry because you

* are a patient or donor involved in blood or bone marrow transplantation;
* are diagnosed with bone marrow failures and receive immunosuppressive treatment, and/or
* receive immune effector cell (IEC) therapy.

We ask your consent to submit your personal data to the EBMT Registry for the purposes described below in section 3.2.

# What will happen to you if you decide to share your data with the Registry?

If you decide to share your data with the Registry, data on your disease, treatment and response to treatment from routine clinic visits will be collected. You will not be required to visit the hospital specifically for this purpose. There are no additional procedures other than normal clinical practice.

If you decide not to share your data or to withdraw at a later date, this will not affect the type or quality of treatment you receive.

# What will happen to your personal data in the EBMT Registry?

## What data is being collected and processed?

According to the European General Data Protection Regulation (GDPR (2016/679)), personal data is defined as any information that relates to an identified or identifiable living individual. For the purpose of the EBMT Registry, the following information from your medical records will be processed:

* Initials, date/year of birth, gender, unique patient number (UPN) given by your hospital and country
* Medical history, physical examination, and results from blood and bone marrow examinations
* Diagnosis
* Transfusions, medication and treatment
* Response to treatment and complications

Personal data that is stored in the EBMT Registry will be linked to your initials, date/year of birth, gender and unique patient number (UPN) given by the hospital. These minimal identifiable data items are necessary to ensure that data collected at different times is accurately stored in the same record. They will not be used to identify you as an individual.

To protect your privacy, your data is given a unique and non-informative database number. This process is known as ‘pseudonymisation’ and is defined in the GDPR. It allows your personal data to be processed in such a way that the data can no longer be linked back to you without the use of additional data which is stored at your local hospital. The EBMT is committed to minimising the sharing of personal data, particularly minimal identifiable patient data. Whenever possible, the EBMT shares pseudonymised data or, when circumstances allow, anonymised data. However, in certain situations, for example to prevent the duplication of data, the minimal identifiable data may still need to be shared, but this will always be done under legally required data protection measures.

## What is the purpose of collecting and processing your data?

**The EBMT Registry**

The primary function of the EBMT Registry is to collect clinical data on patients who have received blood and/or bone marrow transplantation and/or IEC therapy as part of their treatment. The data collected will be used for:

* medical research which aims to further the knowledge base in the field of transplantation, IEC therapy and immunosuppressive therapy
* improving patient care at hospitals through:
	+ providing a reference of treatment results that hospitals can use for quality control
	+ the development of new and improved procedures for transplantation, IEC therapy and immunosuppressive therapy
	+ improving the quality of these procedures through the accreditation of the treating hospitals

Your data in the EBMT Registry will contribute to improvements in patient care and outcome.

The EBMT works with many “Collaboration Partners” internationally, including national registries, national health authorities, and researchers from scientific/clinical institutions. Therefore, we also request your consent to share your personal data with these EBMT partners to fulfil the purpose described above.

For the purposes described below, the EBMT may also work with the European Medicines Agency (EMA; [www.ema.europa.eu/ema](http://www.ema.europa.eu/ema)), national health authorities, Health Technology Assessment bodies, and the marketing authorisation holders (MAHs; the pharmaceutical companies owning the therapies that patients like you are receiving).

**Post-authorisation obligations relating to IEC therapies**

In Europe, IEC therapies can only be used to treat patients after the EMA authorises MAHs to sell their therapy. The EMA may request the MAHs to conduct additional post-authorisation studies to monitor the long-term safety and effectiveness of the product. The EMA has recommended that the MAHs collaborate with the EBMT for the conduct of these studies. For this purpose, the EBMT has developed the ‘EBMT Registry data processing framework for post-authorisation studies on immune effector cells’, which is publicly available on the EBMT website. This framework will allow the EBMT to assist MAHs with EMA imposed post-authorisation IEC therapy studies.

If you are receiving any IEC therapy as a part of your treatment at your hospital, the EBMT requests your consent to share your pseudonymised data in the EBMT Registry with the MAHs of the IEC therapy that you are receiving. This will help the MAHs comply with their obligations to the EMA and national health authorities. This will contribute to a better understanding of the safety and effectiveness of the product(s) you are receiving.

**Health Technology Assessments**

A health technology assessment (HTA) evaluates the social, economic, organisational and ethical impact of a medication or health technology. HTA bodies make these assessments to contribute to health policies that are safe and effective for patients. They also give recommendations on the financing or reimbursement of medications or health technologies by insurers and reimbursement agencies.

Data from the EBMT Registry can be a valuable source of data for HTAs. The EBMT facilitates HTA processes to support that new therapies become available to patients and are covered by national healthcare systems and health insurance policies.

HTA bodies and/or reimbursement agencies may request the EBMT to share pseudonymised data with them for their assessments of specific health technologies. More commonly, the HTA bodies and/or reimbursement agencies request MAHs to provide this data for their specific product. In this case the MAHs will approach the EBMT with the request to share the data necessary. To facilitate the assessments by the HTA bodies and/or reimbursement agencies, EBMT requests your consent to share your pseudonymised data with the MAHs and the HTA bodies and/or reimbursement agencies.

## How is the data stored in the EBMT Registry?

The data is stored in an electronic, certified, secure database of the EBMT and is subject to the European data protection regulations. This database is located in a country that is part of the European Union, and is under a stringent access control policy.

## How long will the data be stored?

The EBMT will hold your data indefinitely so that it can be used in the future for scientific research purposes.

Collaboration Partners will hold your personal data for as long as it serves the purposes described above in section 3.2.

## Who has access to the data in the EBMT Registry?

Access to the data in the EBMT Registry will be limited to EBMT research staff and authorised staff members at your hospital. Upon request from your hospital, access may be granted to your national registries in the field of blood and/or bone marrow transplantation and IEC therapy and/or your disease.

## Who has access to your patient files?

Access to data from your medical records may be needed to verify that the data collection for the EBMT Registry is done accurately and in compliance with current regulations. Access to your hospital medical records will be restricted to:

* the staff at your hospital
* a monitor or auditor who has been commissioned by the EBMT
* regulatory health authorities

All parties have a duty of confidentiality to you as a research participant. We request your consent to allow the above-mentioned access to your medical records for this purpose.

## Will the data in the EBMT Registry be shared with any third parties?

With your consent, your personal data in the EBMT Registry may be shared with the Collaboration Partners for the purposes described above in section 3.2. As part of such collaborations, your personal data may be sent to countries outside of those covered by the GDPR (2016/679). The EBMT arranges GDPR-required safeguards to protect your personal data where it is sent to so-called third countries outside of the European Union that have not been recognised by the European Commission as providing an equivalent level of data protection.

## What is the legal basis for processing the data and who is responsible?

The GDPR (2016/679) regulates the collection, storage and processing of personal data. The purpose of the regulation is to guarantee your privacy. To comply with these regulations, we ask you to give consent as the legal basis for the collection, processing and storage of your personal data in the EBMT Registry for the purposes described in section 3.2.

The EBMT and your hospital are joint ‘controllers’ of your personal data in the EBMT Registry. This means that they both determine the purpose of data processing (why) and the means of processing (how). Both the EBMT and your hospital are responsible for the protection of the data in the Registry.

In the event that your data in the EBMT Registry is shared with health authorities, HTA bodies, MAHs or other scientific/clinical collaboration partners for the purposes described above in section 3.2, these partners will also be a controller of your personal data for that specific purpose and therefore also be responsible for the protection of the data.

## What are your rights (as a data subject)?

You are being asked to consent to your personal data being accessed, stored and processed. If you withhold consent, then your data will not be sent to the EBMT or to any of our collaborators and will not be used for the purposes of research to help future patients.

If you give consent, the data held by the EBMT will continue to be in your control. You have the right to request access to and/or rectification of your personal data or to file a complaint with the national data protection authority. You also have the right to withdraw your consent at any time in the future. Further, you have the right to request that your personal data be erased from the EBMT Registry database and from other databases to which your data may have been exported. This will not affect the type or quality of treatment you receive.

Children and adolescents also have the right to withdraw consent when they come of legal age.

## Are there any extra costs involved if you decide to share your data with the Registry?

No extra costs are involved related to sharing your data and nor will you receive any payment for sharing your data with the Registry.

# Who should you contact for more information or if you wish to exercise your rights?

For more information or if you wish to exercise any of your rights listed in section 3.9, please contact:

[INSERT HOSPITAL DPO]

[NAME, TITLE] [CONTACT DETAILS]

Registry Holder [EBMT]

EBMT Data Protection Officer E-mail: data.protection@ebmt.org

# EBMT REGISTRY INFORMED CONSENT FORM

I have read the Patient Information Leaflet (version 1.0, 26/07/2024), had the opportunity to ask questions and received satisfactory answers. I have had an appropriate amount of time to decide if I want to share my data with the EBMT Registry. I understand that participation is completely voluntary and I am free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected.

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| --- | --- | --- |
| By signing this Consent Form, I acknowledge that: |  |  |
|  | *Yes* | *No* |
| 1. I consent to my personal data, including minimal identifiable data as defined in section 3.1, being reported to and processed by the EBMT Registry and that my data will be kept indefinitely.
 |  |  |
| In addition to the above, |  |  |
| 1. I consent to my personal data, including minimal identifiable 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 my privacy is applied or that sufficient contractual safeguards are arranged if this data is to be sent outside the European Economic Area.
 |  |  |
| 1. I consent to my pseudonymised data in the EBMT Registry being shared with Health Technology Assessment (HTA) bodies and/or reimbursement agencies.
 |  |  |
| 1. I consent to my pseudonymised data in the EBMT Registry being shared with the Marketing Authorisation Holder (MAH) of the IEC therapy I receive 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 my privacy is applied or that sufficient contractual safeguards are arranged if my pseudonymised data is being shared with MAHs that are situated outside the European Economic Area.
 |  |  |
| 1. I give permission to monitors and auditors from the EBMT and regulatory authorities to review my medical records in accordance with applicable laws and under full confidentiality.
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Name of the patient / Name of patient’s legal representative:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

Name of the witness (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

If information becomes available during the period that data is stored in the Registry which may influence the consent of the patient, the hospital will inform him/her in time.

Name of hospital representative:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

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Additional information has been provided by (when applicable):

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position/title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

*Copies to be signed: 1 for the patient, 1 to be stored by the hospital, 1 for the legal representative/impartial witness (delete if not applicable).*