# Patient Information Leaflet for the EBMT Registry

Dear Parents/legal guardians,

You have been given this leaflet because your child, or the child you are legally responsible for, is receiving a blood or bone marrow transplantation, immune effector cell therapy and/or immunosuppressive treatment. We would like to invite you to share your child’s 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 treatment patients receive. The goal of the Registry is to help 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 child’s data with the EBMT Registry; what the purpose of data processing is; which data is being collected; how your child’s data is being protected and what your and your child’s rights are. You are free to decide whether or not you agree to share your child’s 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 child’s data.

If, after reading the information, you agree for your child to take part, you will be asked to sign and date two copies of the consent form. If your child is 12 years or older, he/she will also be asked to sign a form. You and your child will be given one copy to keep and the other copy will remain in your child’s patient file at the hospital. If you decide not to share your child’s data or to withdraw your consent at a later date, this will not affect the type or quality of treatment your child will receive. Please ask your child’s treating physician if anything is not clear or if you would like some more information. Please explain to the child as much as they can understand.

# Summary

| Registry of the European Society for Blood and Marrow Transplantation (EBMT) | |
| --- | --- |
| Aim of the Registry The 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 help 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 child’s data with the EBMT? If you decide to share your child’s data, data on their disease, treatment and response to treatment will be collected from your child’s routine clinic visits. You and your child will not be required to visit the hospital specifically for this purpose. | |
| What will happen to your child’s personal data? All your child’s 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 Officer  E-mail: [data.protection@ebmt.org](mailto:data.protection@ebmt.org)  Phone number: [+34 93 453 8570](tel:%2B34%2093%20453%208570) |

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

You are being invited to share your child’s data with the EBMT Registry because your child

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

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

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

If you decide to share your child’s data with the Registry, data on your child’s disease, treatment and response to treatment from routine clinic visits will be collected. You and your child 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 child’s data or to withdraw at a later date, this will not affect the type or quality of treatment your child will receive.

# What will happen to your child’s 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 child’s medical records will be processed:

* Initials, date/year of birth, gender, unique patient number (UPN) given by your child’s 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 child’s 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 your child as an individual.

To protect your child’s privacy, the 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 child’s personal data to be processed in such a way that the data can no longer be linked back to your child without the use of additional data which is stored at your child’s 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 child’s 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 child’s 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 child’s 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 your child is 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 your child is receiving any IEC therapy as a part of his/her treatment at his/her hospital, the EBMT requests your consent to share your child’s pseudonymised data in the EBMT Registry with the MAHs of the IEC therapy that your child is 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) your child is 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 pseudonymised data of your child 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 child’s data indefinitely so that it can be used in the future for scientific research purposes.

Collaboration Partners will hold your child’s 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 child’s hospital. Upon request from the 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 child’s disease.

## Who has access to your child’s patient files?

Access to data from your child’s 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 child’s hospital medical records will be restricted to:

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

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

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

With your consent, your child’s 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 child’s 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 child’s 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 child’s privacy. To comply with these regulations, we ask you to give consent as the legal basis for the collection, processing and storage of your child’s personal data in the EBMT Registry for the purposes described in section 3.23.1.

The EBMT and the hospital are joint ‘controllers’ of your child’s 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 the hospital are responsible for the protection of the data in the Registry.

In the event that your child’s 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 child’s personal data for that specific purpose and therefore also be responsible for the protection of the data.

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

You are being asked to consent for your child’s personal data being accessed, stored and processed. If you withhold consent, then your child’s 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 and your child have the right to request access to and/or rectification of your child’s personal data or to file a complaint with the national data protection authority. You and your child also have the right to withdraw your consent at any time in the future. Further, you have the right to request that your child’s personal data be erased from the EBMT Registry database and from other databases to which your child’s data may have been exported. This will not affect the type or quality of treatment your child will 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 child’s data with the Registry?

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

# Who should you contact for more information or if you wish to exercise your (child’s) rights?

For more information or if you wish to exercise any of your (child’s) 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](mailto:data.protection@ebmt.org)

Phone number: [+34 93 453 8570](tel:%2B34%2093%20453%208570)

# EBMT REGISTRY INFORMED CONSENT FORM

I have read the Patient Information Leaflet for parents (version 1.0, 8-Jul-2020), 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 child’s 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 child’s medical care or legal rights being affected.

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

Name of the patient

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

Name of the parent (1) or legal guardian: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Name of the parent (2) or legal guardian: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

If information becomes available during the period that data is stored in the Registry which may influence the consent of the parents, 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 parents and/or legal representative, 1 to be stored by the hospital.*