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1. Purpose

The European Society for Blood and Marrow Transplantation (EBMT) maintains an international medical database known as the EBMT Registry. The Registry goes back to the beginning of the 1970's and contains clinical data including aspects of the diagnosis, first line treatments, haematopoietic stem cell transplant (HSCT) or cell therapy associated procedures, complications and outcome.

This Policy regulates the management of Personal Data relating to patients reported to the EBMT Registry. It provides rules and procedures which apply to all departments and individuals within the EBMT. The aim is to ensure that Patient Personal Data is processed and protected properly in all countries and regions and in accordance with the European General Data Protection Regulation (GDPR).

2. Scope

This Policy applies to the Processing of Patient Personal Data by any department or individual within EBMT, in all countries and regions and may extend to other entities and persons by the implementation of agreements and contracts.

3. Definitions

The following definitions of terms used in this document are drawn from Article 4 of the European Union's General Data Protection Regulation:

Personal Data

Any information relating to an identified or identifiable natural person who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, physiological, mental, economic, cultural, or social identity of that natural person. Personal Data includes a natural person's email address, telephone number, biometric information (such as fingerprint), location data, IP address, health care information, religious beliefs, Social Security number, marital status, et cetera.

Sensitive Personal Data

Particularly sensitive in relation to fundamental rights and freedoms, where disclosure of such data could lead to physical damage, financial loss, damage to the reputation, identity theft or fraud or discrimination etc. Sensitive personal data usually includes but not limited to personal data revealing racial or ethnic origin, political opinion, religious or philosophical belief, or trade union membership, as well as genetic data, biometric data (fingerprint) for uniquely identifying a natural person, and data concerning a natural person's health, sex life or sexual orientation.

Pseudonymisation

The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. Article 4 sub (5) GDPR.

Processing

An operation or set of operations which is performed on Personal Data, whether by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval,

consultation, use, disclosure, transmission, dissemination, restriction, erasure, or destruction of the data.

Data Controller

The natural or legal person, public authority, agency or any other body, which alone or jointly with others, determines the purpose and means of the Processing of Personal data.

Data Processor

Means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

4. Responsibilities

The EBMT employees and any entities and persons by the implementation of agreements and contracts with EBMT are responsible for complying with this Policy.

The EBMT Unit Managers are responsible for the implementation and management of this policy by:

- Implementing procedures to make this policy operational.
- Educating staff to understand and data processing procedures.
- Ensuring data is processed in accordance with agreements in place.
- Release only anonymized, de-identified or limited datasets that are compliant with applicable laws and regulations.

5. General Principles for Processing Personal Data

The EBMT ensures that all personal data under its responsibility is processed according to the GDPR and the information provided in the informed consent given by the patients and/or donors is:

- Processed lawfully, fairly and in a transparent manner in relation to the data subject;
- Collected for scientific research legitimate purposes;
- Processed adequately, relevantly and limited to what is necessary in relation to the purposes for which they are collected and/or further processed;
- Accurate and up to date;
- Kept for an unlimited period in a form which permits identification of data subjects for no other purpose than historical, statistical or scientific research purposes;
- Processed in a manner that ensures appropriate security of the personal data through technical and organisational measures.

6. Legitimate Purposes for Processing Patient Personal Data

EBMT departments or individuals may process patient Personal Data for legitimate purposes which include but are not limited to:

Clinical Research and improvement of patient care. The EBMT Registry collects data for research and development among others of new and improved transplant, immune effector cell therapy and immunosuppression procedures, and to improve the quality of these procedures through the accreditation of treatment units

Processing operations related to reliability and safety purposes. The Processing of patient Personal Data to comply with a legal obligation, for example: the processing of personal data in the

context of safety reporting, an inspection by national competent authority, the retention of clinical trial data in accordance with archiving obligations set up by the clinical trial regulation or relevant national laws, have to be considered as necessary to comply with legal obligations to which the sponsor and/or the investigator are subject.

7. Data Collection

The EBMT works in partnership with local healthcare providers to collect data on patients undergoing bone marrow or stem cell transplantation, immune effector cell therapies, and immunosuppressive treatments for any disease. Personal identifiable data is limited to patient initials, date of birth, and gender. These items are necessary in order to ensure that data collected at different times and/or at different hospitals is accurately stored in the same record. It is not used and cannot be used for identification of the individual. This process is known as pseudonymisation and is defined in the GDPR regulations. Each patient's report is given a unique and non-informative database number which is the one used for research purposes. Nobody outside the hospital where the patient is treated will be able to identify an individual from the data stored.

Following the GDPR, and to ensure the maximum accordance with the law of all EU/EEA nations, personal data of patients residing in EU member countries shall only be used for research through EBMT when appropriate informed consent is provided. This has been common practice for many years already.

The signed patient informed consent is obtained by the individual centres or donor registries submitting data to the EBMT to make sure that the respective national laws are followed. Technical and functional separation between the EBMT Registry and treating centre is key in order to protect the patient privacy rights, medical records or other sensitive patient information showing the identity of the patient are recorded in the treating centres and are not reported to EBMT.

The patient informed consent is a prerequisite for EBMT for submitting the data and provides all necessary information about usages of the data, to ensure appropriate consent is obtained in all cases.

EBMT and the Reporting Centres are joint controllers for the Registry data. The Reporting Centre determines the means and purpose of the data processing of its own data reported. However, EBMT determines how the data is processed for the purpose of the registry.

7.1. EBMT Responsibilities

EBMT will follow data policies and procedures regarding data collection and management, including those specific to data protection and safety, access and sharing including but not limited to:

- (a) Use Personal Data only as necessary for the performance of its obligations under terms of implemented agreements;
- (b) Ensure that access to the Personal Data is limited to only those staff members who have a legitimate purpose to access the Personal Data and that all personnel who have access to and/or use Personal Data are obliged to keep the Personal Data confidential;
- (c) Maintain complete and accurate records of any use of Personal Data it carries out to demonstrate its compliance with the Joint Controllership Agreement, GDPR and Informed consent provided;
- (d) Assist Centres in responding to any request from a Data Subject and in ensuring compliance with its obligations to all Data Protection regulations with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;

(e) Notify Centres without undue delay of becoming aware of any Personal Data breach; such notice to include all information reasonably required by Centres to comply with reporting obligations under Data Protection regulations;

(f) Promptly notify Centres of any communication from a Data Subject regarding the processing of their Personal Data, or any other communication (including from a regulatory authority) relating to either Party's obligations under the Data Protection regulation in respect of the Personal Data;

(g) Employ ongoing oversight to the privacy and security obligations to ensure that internal controls are suitably designed and operating effectively to protect against reasonably foreseeable risks to the data, including, but not limited to, auditing of the privacy and security safeguards based on recognized industry best practices;

(h) Assign a qualified data protection officer, or information security official, when core use activities include large-scale genetic, ethnic or racial personal information meeting relevant requirements;

(i) Not transfer any Personal Data across international borders unless the following conditions are fulfilled:

1. A Party has provided appropriate safeguards in relation to the transfer;
2. The Data Subject has enforceable rights and effective legal remedies; and
3. The Party acting as Data Processor complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred; and

(j) At the written direction of Centres, inactivating Personal Data on termination or expiration of the Agreement unless such Personal Data is allowed to be maintained by applicable law.

7.2. Centre Responsibilities

Institutions submitting data to the EBMT are expected to comply with their country's laws and regulations governing human subjects and privacy protection, and to obtain explicit individual consent to data submission to EBMT.

8. Use of Registry data

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 Immune Effector Cell (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 main use of this data is clinical research, but it will also be used to support the mission of the EBMT in aspects such as the inspection, auditing and accreditation of transplant centres.

8.1. EBMT led studies

The EBMT registry can use all the data submitted to them. It is understood that data submitted to the EBMT can be used for research and published by the EBMT WPs as long as the existing **Guidelines for the Conduct of Registry Studies** using the EBMT Registry Database and the **Authorship guidelines for EBMT publications** are followed. Both documents are mandatory reading for any WP investigator wishing to perform a registry study.

Member centres use the Registry to store their own data while simultaneously making it available to the EBMT. Each EBMT member can be considered as the Controller of their data, although it is understood that the owner is the patient. The Reporting Center determines the means and purpose of the data processing without having to require permission or notify the EBMT and can contribute to the EBMT Registry studies through participation in the EBMT Working Parties.

8.2. Donor registries

Donor Registries can use the Registry to store their own data while simultaneously making it available to the EBMT. Donor Registries determine the means and purpose of the data processing without having to require permission or notify the EBMT. Donor Registries have access to their own data at all times.

Donor registries may also request access to the Registry in order to follow the donors or the patients that have received donations from them. In the latter case, the centre must give permission for the Donor Registry to be able to see selected patient data.

8.3. National registries

National registries operating in some countries, usually under the umbrella of a medical association, have become part of the EBMT data flow by mutual consent and are using the same central database. These national registries have implemented Data Sharing Agreements with EBMT and can use their data for their own purposes, which may encompass national requirements for registration of transplants, research, demographics, etc. Where these registries exist, the responsibility of the EBMT Registry for data quality may be partially devolved to them. Belonging to a national registry does in no way preclude the centre from exercising their rights as EBMT members, and they have as much access to the Registry staff and services as any other member centre.

8.4. Study groups

Groups of centres can set up studies and use the EBMT Registry as their database. Via a request to EBMT to set up a study group and its corresponding series of permissions to access the data. Such requests must be submitted together with explicit permissions from the principal investigators of the involved centres. All centres must be members of the EBMT. A procedure document with a request form template is available for this purpose.

8.5. International research organisations

EBMT has implemented data sharing agreements with some international research organisations. Some centres that submit data to these research organisations can request the EBMT to provide these organisations access to their data, so they do not have to do double reporting. In these cases, the EBMT can set up virtual “registries” that replicate the scope of the organisation and provide access to a data manager of this organisation to access the permitted data. Such requests must be submitted explicitly by the principal investigators of the involved centres. All centres must be members of the EBMT. A procedure document with request form is available for this purpose in the EBMT Website: <https://www.ebmt.org/registry/data-sharing#natreg>

8.6. Corporate sponsors

Corporate members who are EBMT Partner of Excellence can submit a request to EBMT for obtaining a data report or for collaboration on a study.

8.7. Marketing Authorisation Holders and other Third Parties

EBMT will not sell, distribute or lease personal data to third parties unless the data subject has provided EBMT with his or her consent and it is allowed by law.

Pharmaceutical Companies, Institutions or non-profit Organisations may receive data for performing pharmaco-epidemiological studies. EBMT will implement collaboration and data sharing agreements with third parties that clearly define the roles of responsibilities of each party.

EBMT is committed to data transparency with intent to share data to support the scientific community and public interest. Any agreement to data sharing will be reviewed and approved at the time of request and data minimisation measures will be applied. Medical data sent in the context of EBMT research projects will be identified by the non-informative database number, and items such as date of birth, initials or the hospital UPN will not be exported.

8.7.1. Primary Use of Data

Primary collection of data for a specific study (i.e. where the events of interest are collected as they occur specifically for the study).

In the case of primary collection of data the regulatory Sponsor of the study defines which data is collected from study participants to answer the study's main research questions. Generally this means that data collection forms and informed consent forms need to be developed and submitted for regulatory and ethical approval. Contractual agreements with the regulatory Sponsor should be in place to clearly define the roles and responsibilities of each party for implementing requirements for the study, including but not limited to data collection, analysis, regulatory submissions and safety reporting. Individual studies for regulatory purposes within a centralised procedure, using the cellular therapy module of the EBMT registry, should be conducted under a study protocol that is approved by EBMT and agreed with regulatory authorities, before study starts.

8.7.2. Secondary Use of Data

Secondary use of registry data collected routinely (i.e. where the events of interest have already occurred and have been collected for another purpose)

In the case of secondary use of registry data the data collection for the study is based on standard EBMT Registry procedures, data collection forms and informed consent form. For studies based on secondary use of registry data the submission of suspected adverse reactions in the form of ICSRs is not required. EBMT collects adverse events of special interest through the standard registry data collection forms, allowing aggregated analysis on the incidence of these events. Centres have the responsibility to report suspected adverse reactions associated with medicinal products as a spontaneous report to a MAH or competent authority.

8.8. Government agencies

Registry data may be accessed by public agencies in one of two ways:

(1) they can request direct access to data submitted by centres in their country. As with any other type of access, centres need to make the request to the Registry for their data to be accessed directly by these agencies.

(2) National registries may collaborate with public agencies providing them with data extracted from the EBMT Registry.

8.9. 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 and appropriate data sharing agreements shall be implemented before the data is shared.

9. Data Privacy

EBMT is committed to guarantee the confidentiality and security of the EBMT Registry Patient Data. All EBMT employees are committed to keep confidentiality in relation to personal data to which they may have access for the performance of their job, contractual responsibility or any other kind of responsibility. EBMT employees shall not use any confidential information to which they have access under the Contract for purposes other than those set forth in the Contract, being expressly prohibited the disclosure of Personal Data.

EBMT staff follow a standard procedure for the creation of anonymized, pseudonymized or de-identified datasets in projects that specifies removal of all patient, donor, and centre identifiers, which could lead to the identification of a patient or transplant centre from data files.

EBMT will not release identifiable patient or centre variables unless these data are critical to the approved study / project or will be used for linking to another data file via an established collaboration agreement.

In cases of an approved study or project or when datasets are requested from previous research, the requestor must submit a proposal to the EBMT WP that specifies the requirements for using the EBMT data before final approval of the project.

10. Data Security

Data submitted to EBMT is protected by safeguards ensuring security and stringent access control as described in its Standard Operating Procedures. The EBMT has implemented standard security practices and controls to protect data; maintains a System Security Plan of management, operational and technical controls.

Registry data is entered and maintained in a central database with Internet access. Each EBMT centre is represented in this database and users from a centre can enter, view, modify, obtain reports and download their own data once the necessary permissions have been granted by the Principal Investigator of the centre. In addition, all EBMT member centres can obtain general overviews of the complete EBMT data. The database is run and accessed through a system called ProMISe (Project Manager Internet Server) and soon will be migrated to a new platform.

10.1. ProMISe

ProMISe (Project Manager Internet Server) is a web based relational database management system for the design, maintenance and use of (clinical) data management. ProMISe provides custom made databases for scientific medical research, including an application for on-line data entry, quality checks, online questionnaires and reporting. It also provides a tool for data retrieval to facilitate statistical analysis. ProMISe can be applied for single- as well as for multi-center studies.

ProMISe is ISO/IEC 27001:2013 and NEN7510 certified; data stored within ProMISe automatically comply with the most recent requirements regarding the storage and privacy of medical data. The certificate-holder is Leiden University Medical Center (LUMC) who hosts the database in The Netherlands and is subject to the regulations of the General Data Protection Regulation (GDPR) issued by the European Union. Only European countries that follow this regulation, regardless of whether they are members of the European Union or not can host the EBMT Registry database.

- ADM Information Security Policy Statement
- Certificaat ISO27001 (ID 5055)
- CERTIFICERING2013 (ID 1523)
- Information Access Policy Statement

11. Methods for Data Transfers

The EBMT works with many researchers on international collaborations across scientific or clinical institutions and so, under previously gathered patient consent and implemented collaboration and data sharing agreements between the parties. The patient pseudonymised personal data may be sent to countries outside the EEA that are provided with the same level of protection for privacy. When personal data is transferred outside the European Economic Area, special safeguards are required by the EU General Data Protection Regulation (2016/679) to ensure that the protection travels with the data. Those safeguards are listed below, and the implementation will be subject to the country and/or institution:

- The European Commission has adopted an adequacy decision on the country as providing adequate protection.
- European Commission Standard contractual clauses for data transfers between EU and non-EU countries.

EBMT will not sell, distribute or lease personal information to third parties unless we have the subject's permission or are required by law to do so.

12. Comments or questions

If you have any comments or questions about this personal data protection statement, please send them to Data.Protection@ebmt.org

13. Reference documents

- EU GDPR 2016/679 (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC)
- Privacy Policy <http://www.ebmt.org/privacy-policy>
- EBMT Registry Function Document
- EBMT Guidelines for the Conduct of Registry Based Studies using the EBMT database

Appendix

Links

Please note: links are only correct at time of printing

Linked to Controlled Document

Changes In This Version

APPROVED CHANGE REQUESTS

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Change requested by Eoin McGrath (Inactive) on 21-Oct-2020

Page 4 has a track-change in red.

Approved by Iris Bargallo on 04-Nov-2020

Approver Comments:

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Nienke Zinger (Inactive) Requested Change: 'Page 8, second line: pseudonymized instead of seudonymized (typo)'

Change Requested on 21-Feb-2022 16:11 by Iris Bargallo

Anja Henseler Requested Change: '

Should be subject's ?

EBMT will not sell, distribute or lease personnel personal information to third parties unless we have the subject' permission or are required by law to do so.'

Change Requested on 21-Feb-2022 16:11 by Iris Bargallo

Anja Henseler Requested Change: 'page 7:

For studies/projects, EBMT staff follow a standard procedure for creation of anonymized, seudonymized or d'

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Should be subject's ?

EBMT will not sell, distribute or lease personnel personal information to third parties unless we have the subject' permission or are required by law to do so.'

Change Requested on 27-Dec-2020 19:05 by Anja Henseler

Anja Henseler Requested Change: 'page 7:

For studies/projects, EBMT staff follow a standard procedure for creation of anonymized, pseudonymized or d'

Change Requested on 27-Dec-2020 19:05 by Anja Henseler

Anja Henseler Requested Change: '8.7. Corporate sponsors Corporate members have the right to access the Registry database to obtain aggregate anonymised data where neither the patient nor the centre are identifiable.

Question:-> This means the Corporate members should NOT be able to access the Registry Database. They receive reports from the Study Coordinators '

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Minor changes were made to EBMT 15 by Iris Bargallo on 22-Dec-2020, Expiry Date was removed, Authors were set to Iris Bargallo, Procedure was changed to EBMT_P_010_01_EBMT_Data_Use_and_Processing_Poli There is a non-accepted change .

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Lissa Perteghella verified change request: ""

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Authorisation

This document was securely signed and authorised by :

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