EBMT

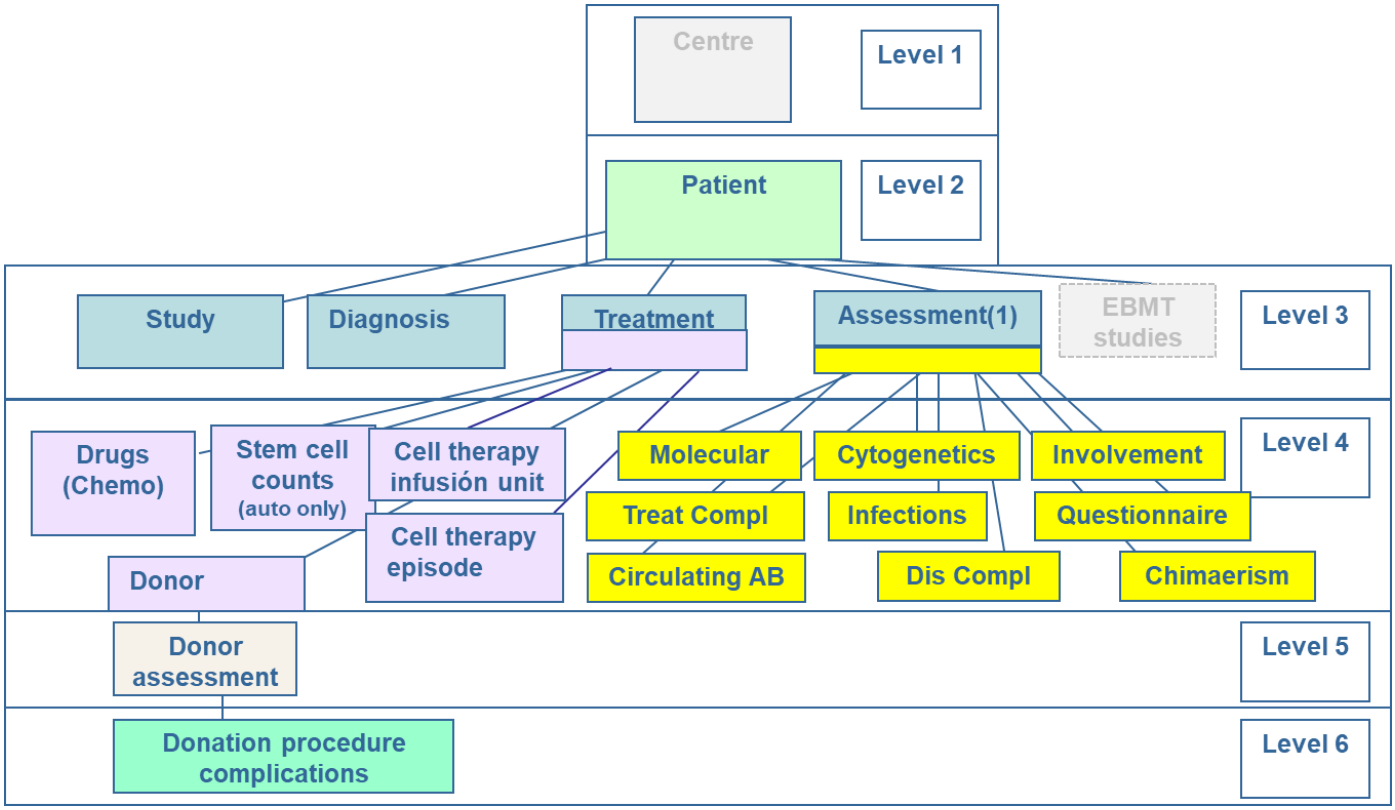
European Group for Blood and Marrow Transplantation

THE EBMT REGISTRY DATABASE

For registration of

ALLOGENEIC or AUTOLOGOUS

Stem Cell
Transplantation



LEVELS

The structure of the database is hierarchical and the number of levels is six. All tables contain "navigation" items which are used by the designer to support data entry but which have no reflection on the clinical items or registry data quality items. All tables also have database administration items to enable proper functioning inside ProMISe. These items will not be discussed.

The number of items has been described as "less than" as the exact number of items used for each record will vary depending on which forms are being entered.

LEVEL 1

This is the CENTRE table. It contains essential information for each transplant centre. Each transplant centre is one record and the Centre Identification Code (CIC) is the unique primary index (PI). This table is not physically present in the database but is conceptually present.

LEVEL 2

PATIENT (AA_) (<160 FIELDS)

- patient data, which will not change throughout the lifetime of the patient, such as date of birth, initials, date of death, etc. Each patient is one record. The combination of items ID (centre identification) and IDAA (patient identification in that centre) uniquely identify each record and constitute the PI.
- administrative variables to be used for monitoring data quality, or to permit viewing flexibility in circumstances such that a patient may need to be shared among various centres; this may happen, for example, when a patient receives a second transplant in a different centre from that which transplanted him/her before, or when a patient is being followed up away from the transplant centre, or when a harvest centre wants recognition for the harvest.
- summary of the registration: dates of transplants, last survival status, last date seen
- a reference to the STUDY table where information regarding studies affecting this patient is kept.

LEVEL 3

The bulk of the database will be at this level. It consists of five tables. All these tables share the PATIENT table as their parent table.

The PI of three tables is the ID, IDAA combined with the date the data was collected. This date may differ from table to table, since a record is created in a table only if data needs to be stored in that table.

The other two tables contain study information, either for the use of the centre storing data requested in the MEDAB forms, or for the use of the EBMT storing data for the administration of an EBMT study. These tables are indexed with an integer.

STUDY (BA_)(≤20 fields)

This table is only used if the patient has been entered into a prospective study. This is a data item in the MEDAB forms. Contains:

- Information pertaining to treatment allocation, and number in the study, etc., but only the name of the study is requested in the MEDAB forms.
- The PI is defined with an integer.

DIAGNOSIS (BB_)(≤140 fields)

The table contains all the information pertaining to all diagnoses. It does not contain staging information which may be repeated at several time points for the same patient (i.e.: lymph nodes involved, haptoglobins in serum, etc.). It does, however, contain information that is requested only at diagnosis in our forms (i.e.: estrogen receptor status) but which in itself could have been requested at other time points.

The date in the PI is the date the diagnosis was made. Most patients will only have one record in this table. However, patients, who 1) developed a secondary disease after the transplant, or 2) have two diseases simultaneously for which transplant can be an indication, or 3) whose transplant diagnosis was secondary to a prior diagnosis may have as many records as diagnoses registered. The diagnoses are differentiated as to whether or not they are indication for transplant.

TREATMENT (BC_)(≤270 fields)

The table contains all information pertaining to all treatments received by the patient. This includes lines of treatment given to the patient before the first transplant ever, all the transplants, any treatment between transplants, treatment for relapse or progression, pre-emptive treatment, etc. All the treatments, regardless of the time point or reason for them, share the same database fields. For example, the same field will be used for chemotherapy given (yes/no/unknown) as 1st line treatment, for mobilisation, for conditioning, for relapse, for a second mobilisation, for a second conditioning, etc.

Treatment at each time point is contained in a different record. Therefore, one single patient may have several treatment records. However, there will only be one record for each treatment even if the treatment is made up of several therapies such as different chemotherapies, plus radiotherapy, plus serotherapy, if given at very short intervals from one another. The date used for the PI will be the very first date that particular treatment started. This is to avoid a needless proliferation of records within a very short period of time.

It contains:

- Indication for the treatment
- Type of treatment
- Characteristics associated to the treatment (sequential number, etc.)
- Response or status after this particular treatment

This table is parent to level 4 tables in which a more detailed description of the treatment (chemotherapy or drugs, autologous progenitor cell infusion, donor characteristics) can be registered.

ASSESSMENT(1) (BE_)(<650 fields)
The table contains all investigations performed at different patient assessments. This includes haematology, biochemistry, staging, organs involved, bone metastasis, etc. The number of records per patient is indefinite, although they will usually coincide with the standard time points of diagnosis, 1st line treatment, transplant, response, progression, etc. This is the largest table, both in terms of records and of items. The date used for the PI is the date of the investigation.

- Type of investigations done (cytogenetics, molecular, scans, etc.)
- Biochemical and haematological values
- Disease involvement
- Clinical abnormalities
- Staging including the current disease status in terms of CR, PR, etc.
- History of the disease until that point
- Serological profile
- Physical state
- Incidence of complications, including GvHD
- Engraftment and chimaerism status
- Transfusion status
- HLA

This table is parent to level 4 tables in which a more detailed description of some of the assessments (complications, cytogenetics, infections, involvement, molecular markers, associated clinical problems, circulating antibodies, questionnaire items) can be registered.

EBMT STUDIES (BI_)(≤15 fields)
This table is only used if the patient has been entered into an EBMT study. Its use is restricted to EBMT staff.

- Information pertaining to the name and type of study
- Fields to aid WP study co-coordinators to keep tabs on data queries, mailing, completeness of the data, etc.
- The PI is defined with an integer initiated with the CIC assigned to the WP

LEVEL 4

This level contains mostly a series of smaller tables, children to one of the tables in Level 3 that have a date as third part of the PI. It allows detailed description of investigations or treatments mentioned in the parent tables. The PI is made of the ID and IDAA, the date of the parent table, and the type of information being stored (chemotherapy regimens for treatment, chromosome abnormalities for cytogenetics, etc.) Each type is stored in a separate record. The addition of new types does not require the addition of new fields, but the addition of a new label to the label set which describes it.

All Level 4 tables correspond to a leading question in the parent table at Level 3. A positive answer in the leading question is what leads the user to create and fill in information in the Level 4 table.

TREAT COMPL (CA_)(≤15 fields)
This table is the child of the ASSESSMENT(1) table. It stores complications which are considered a consequence of the treatment. When complications are indicated as present in the ASSESSMENT(1) table, these complications can be described in the TREAT COMPL table. There is no limit to the number of complications that can be added at any time point. The last PI is the complication itself.

CYTOGENETICS (CC_)(≤15 fields)
This table is the child of the ASSESSMENT(1) table. When cytogenetic investigations are done, this is indicated in the ASSESSMENT(1) table. A full description can then be entered in this table. There is no limit to the number of abnormalities that can be added at any time point. Information on whether an abnormality was or was not present can also be added. The last index of the PI is the abnormality itself.

INFECTIONS (CG_)(≤20 fields)
This table is the child of the ASSESSMENT(1) table. It stores infections associated to the treatment. When infections are indicated as present in the ASSESSMENT(1) table, these infections can be described in the INFECTIONS table. There is no limit to the number of infections that can be added at any time point. It allows entry of type of infection, pathogen,

method used for isolation, length of episode, number of days hospitalised for the episode, etc. The last key of the PI is a number with no intrinsic significance which serves only for the purpose of rendering the record unique.

INVOLVEMENT (CK_)(≤10 fields)
This table is the child of the ASSESSMENT(1) table. It stores organs and type of involvement. When organ involvement is indicated as present in the ASSESSMENT(1) table, these organs can be described in the INVOLVEMENT table. There is no limit to the number of involvements that can be added at any time point. It allows entry of organ involved, type of involvement, presence or absence, whether primary or metastatic, etc. The last key of the PI is the organ involvement itself.

MOLECULAR (CL_)(≤10 fields)
This table is the child of the ASSESSMENT(1) table. When molecular investigations are done, this is indicated in the ASSESSMENT(1) table. A full description can then be entered in this table. There is no limit to the number of markers that can be added at any time point. Information on whether a marker was or was not present can also be added. The last key of the PI is the marker itself.

CHIMAERISM (CM_)(≤25 fields)
This table is the child of the ASSESSMENT(1) table. It stores the chimaerism details, such as cell types tested, percentage chimaerism, etc., for allograft patients only. There is no limit to the number of tests that can be added at any time point but the tests should have been done within a reasonable time period, after and within a year after the date of the parent assessment record. The last key of the PI is the date the chimaerim tests were done.

DIS COMPL (CN_)(≤5 fields)
This table is the child of the ASSESSMENT(1) table. It stores complications which are considered a consequence of the diagnosis. Currently it is only in use for Autoimmune diseases. When complications are indicated as present in the ASSESSMENT(1) table, these complications can be described in the DIS COMPL table. There is no limit to the number of complications that can be added at any time point. The last key of the PI is the complication itself.

CIRCULATING AB(CO_)(≤5 fields)
This table is the child of the ASSESSMENT(1) table. It stores the presence of antibodies in the patient. Currently it is only in use for Autoimmune diseases. When antibodies are indicated as present in the ASSESSMENT(1) table, these antibodies can be described in the CIRCULATING AB table. There is no limit to the number of antibodies that can be added at any time point. The last key of the PI is the antibody itself.

QUESTIONNAIRE (CP_)(≤15 fields)
This table is the child of the ASSESSMENT(1) table. It stores the answers to quality of life and disease symptoms questionnaires. Currently it is only in use for Autoimmune diseases. When questionnaires are indicated to have been used in the ASSESSMENT(1) table, the answer to each question can be described in the QUESTIONNAIRE table. There is no limit to the number of questions that can be added at any time point. The last key of the PI is the question itself.

DRUGS (CHEMO) (CD_)(≤25 fields)
This table is the child of the TREATMENT table. It allows for entry of details related to any drug treatment such as chemotherapy regimen, dose, brand, duration of treatment, route of administration, number of cycles and the date at which each particular therapy –within the same treatment- started and ended. The last key of the PI is the drug/regimen itself.

STEM CELL COUNTS (CF_) (<10 fields)
This table is the child of the TREATMENT table. It allows for entry of all cell counts relating to the autologous cells actually infused during transplant or the donor cells infused in cell therapy. The type of cell, counts and the timing of the measurement are stored here. The last key of the PI is a code indicating the combination of source of the stem cells and the timing of the measurement.

CELL THERAPY INFUSION UNIT (CE_) (<120 fields)
This table is the child of the TREATMENT table. It contains detailed information on the composition of the cell therapy units which are not considered transplants. The type of cell, manufacturing process and manipulation is stored here. The last key of the PI is a number with no intrinsic significance which serves only for the purpose of rendering the record unique.

CELL THERAPY EPISODE (CQ_) (<50 fields)
This table is the child of the TREATMENT table. It allows for entry of all cell counts relating to cell therapy and their route of infusion.. The last key of the PI is the date the cell infusion episode started.

DONOR (CH_)(<225 fields)
This table is the child of the TREATMENT table. It enters all the donor information such as donor identification, donor registry, serological profile, sex, age, cytokine administration, HLA, donor cell manipulation, infused cells, etc. Since this table is the child of a transplant record in the TREATMENT table, it can have as many records as necessary thus allowing for multiple donors. This table is parent to another table in which follow up assessments of the donor is stored. The last key of the PI is a number with no intrinsic significance which serves only for the purpose of rendering the record unique.

LEVEL 5

There is only one table at this level, which is used to record donor assessments, and is a child of the table where the donor is registered.
Cell
DONOR ASSESSMENT (DB_)(<80 fields)
This table is the child of the DONOR table. It records the assessment of the donor at the time of harvest and at follow up. It contains information on the medical history and medication of the donor. The last key of the PI is the date of the donor assessment. Access to this table is only given to users who have permission to view donor data.

LEVEL 6

There is only one table at this level, which is used to record severe adverse events (SAE) for the donor, and is a child of the donor assessment table.

DONOR ASSESSMENT (EA_)(<5 fields)
This table is the child of the DONOR ASSESSMENT table. It records the SAE of the donor at the time of harvest and at follow up. It contains a few attributes of the SAE. The last key of the PI is a numeric rendering of the ICD 10 code for the SAE. Access to this table is only given to users who have permission to view donor data.