EBMT

European Society for Blood and Marrow Transplantation
in collaboration with
Swiss Transfusion SRC

DONOR OUTCOME DATA MANUAL

A Guide to the completion of the EBMT Donor Outcome Data Forms

Table of Contents

INTRODUCTION

The present document contains information on how to fill in **Donor outcome data** as requested through the associated data collection forms. These forms are based upon the **Minimal Data set** approved and recommended by the Worldwide Network for Blood & Marrow Transplantation (WBMT) in 2011[1]

It is preceded by the definition of a collection of haematopoietic stem cells (HSC) or other type of donor cells such as donor lymphocytes (DL), and information on when new registrations or follow up should be submitted.

Reporting of **Donor outcome Data** is done through two data collection forms:

- *Report on donation procedure and up to 30 days after*
- *Long term follow up report after last donation procedure*

Both forms, together with this manual, can be downloaded from the *Data collection forms* section of the *Data management* page of the EBMT website, at:

http://www.ebmt.org/Contents/Data-Management/Pages/Data-Management.aspx

There you will also find instructions on how and when to submit data to the EBMT.

We are grateful for any feedback as to its content (clarity of the definitions, omissions, insufficient background or excessive verbosity, etc.). Please send all comments to the EBMT Central Registry Office to the attention of Shelley Hewerdine at shelley.hewerdine@ebmt.org

[1] *Halter JP, van Walraven SM, Worel N, Bengtsson M, Hägglund H, Nicoloso de Faveri G, Shaw BE, Schmidt AH, Fechter M, Madrigal A, Szer J, Aljurf MD, Weisdorf D, Horowitz MM, Greinix H, Niederwieser D, Gratwohl A, Kodera Y, Confer D.* Allogeneic hematopoietic stem cell donation: standardized assessment of donor outcome data-A WBMT consensus document Bone Marrow Transplant 2012 Jul 9. doi: 10.1038/bmt.2012.119. [Epub ahead of print] PubMed PMID: 22773129

DEFINITION

-Donation procedure: procedure where the objective is to collect an adequate number of therapeutic cells (HSC, MSC, DLI, other e.g. NK) to be used in another individual.

Start: the donation procedure starts with the first injection of a mobilizing agent, the start of anesthesia or the start of apheresis (in case of non-stimulated leucapheresis, e.g. for DLI).

Even if the preparative actions (i.e. start of injections, apheresis or anesthesia) are **stopped** prematurely (due to donor or recipient reasons) the activity fulfills the definition of a donation procedure and the donor should be **registered and followed**.

☞ *Donor Registries: See APPENDIX IV: Create a dummy patient if donor outcome data cannot be linked to the recipient registration*

-Donor: a person who is the source of cells or tissue for a cellular therapy product.

-***Collection*****:** any procedure for procuring a cellular therapy product regardless of technique or source. *(Synonym: harvest)*

-Product:

PBSC: HSC hematopoietic stem cells collected in peripheral blood by apheresis

BM: Bone marrow as a source of hematopoietic stem cells or mesenchymal stem cells

Unstimulated leukapheresis: e.g. donor lymphocytes (DLI), etc. collected by apheresis or blood donation.

Other: Any other therapeutic cells

-Serious events and adverse reactions (SEAR)

The concept of SEAR is used by the World Marrow Donor Association (WMDA) and is harmonised with the World Health Organisation (WHO).

They include:

Serious Adverse Event (SAE):

Any unintended or unfavorable sign, symptom, abnormality, or condition temporally associated with an intervention that may or may not have a causal relationship with the intervention, medical treatment, or procedure.

Serious Adverse Reaction (SAR):

An unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

For more information, see:
http://www.worldmarrow.org/index.php?id=493&type=1

REGISTRATION OF A NEW DONOR REPORT

A new ***Report on donation procedure and up to 30 days after*** should be submitted as soon as possible after 30 days have elapsed since the end of the procedure.

Each donation procedure must have its own report. Note the following guidelines:
Submit one form if:

- There is only one donation of bone marrow (BM) stem cells
- There is only one donation of peripheral blood (PB) stem cells
- There is only one donation of Donor lymphocytes (DL)
- There is a donation of PB stem cells, followed by a donation of BM stem cells, within a period of a week

Submit two forms if:

- There is a donation of BM, followed by a donation of PB. Each of these donations should have its own form.
- The interval between two donations is more than a week

☞***Donor Registries****:* In the current Registry system as used by the EBMT, the unrelated donor outcome data cannot be linked to the patient record directly. This has to do with data protection of the donor data and the consent provided by the donor which may not allow centre data managers to see the donor follow up when the latter is unrelated.
For this reason, donor registries that want to use the sytem for donor follow up will be issued with their own CIC where they can enter the donor data in agreement with the donor consent and data protection: *See APPENDIX IV: Create a dummy patient if donor outcome data cannot be linked to the recipient registration*

☞ *ProMISe Users: to enter reports on **related** donors, please load the existing patient record in ProMISe and add the donation procedure (30 day report) using code 7 in the first field "Form about to entered". Long term follow up for donors is entered in the same record using code 8 in that same field.*

The data entry must be done in the following order for the programmed navigation to work:

1. *Full MED-A or B (day 100) must be entered first before any donor assessments can be entered. If you are also adding information to donors used for non HSCT procedures (e.g. DLI, mesenchymal), note that those therapies must already be entered.*
2. *Donor Donation Procedure(s) - day 30*
3. *Donor Follow Up – after 1 year, then as below. (If there is no Donation Procedure record, you will not be able to enter any follow up).*

SUBMISSION OF ANNUAL DONOR FOLLOW UP

The first submission of the ***Long term follow up report after last donation procedure*** should be submitted as soon as one year has elapsed from the date of the procedure.

After that, we recommend that it be submitted every two years up to 10 years. The minimum submission should be after 5 years and again after 10 years.

If a patient has had multiple infusions using the same donor, it is not necessary to send long term follow ups per infusion.

☞ *ProMISe Users:* should enter the follow up on the most recent donation record.

Donor outcome

Report on donation procedure and up to 30 days after

TRANSPLANT CENTRE AND RECIPIENT IDENTIFICATION

EBMT CIC _____
(if known)

EBMT database number _____
(if known)

Center of HSCT: _____

Hospital/unit: _____

Unique Patient Number or Code ……

Initials: _____ _____(first name(s)_surname(s))

Date of birth: _____ ____ ____
yyyy mm dd

Date of HSCT: _____ ____ ____
yyyy mm dd

PRODUCT

☐ BM (Including collection of MSC)
☐ PBSC
☐ Both *(*BM and PBSC)
☐ Unstimulated leukapheresis
(e.g. donor lymphocytes (DLI), etc.)
☐ other, specify _____

DONOR DATA

Donor number/ID……

Donor signed Informed consent for data transmission to the EBMT Registry ☐
Compulsory, registrations will not be accepted without this item!

Initials: …… …… first name(s)_surname(s))

Relationship to recipient:

☐ syngeneic (identical twin)
☐ identical sibling/non identical twin
☐ other family member: ☐ matched ☐ unmatched
Describe relation _____ to the recipient *(aunt, uncle, first cousin, etc.)*
☐ unrelated donor

Date of birth: _____ ____ ____
yyyy mm dd

Sex: ☐ male ☐ female

DONATION PROCEDURE

First day of this collection: _____ ___ ___
yyyy mm dd

COLLECTION DATA

EBMT Code (CIC): ……
(If known)
Collection center: ……

Donor registry:
……

Contact person: ……

Date of this report: _____ ____ ____
yyyy mm dd

Start date of donation procedure: _____ ___ ___
yyyy mm dd

Chronological Number of this donation procedure: _____
If >1: Same recipient ☐ no ☐ yes

Centre of previous donation: ……
Date of previous donation: _____ ____ ____
yyyy mm dd

Was the product collection completed? ☐ no ☐ yes

Were haematopoietic growth factors used? ☐ no ☐ yes
(eg GCSF) if yes, specify……..
Were cell binding inhibitors used, ☐ no ☐ yes
(eg Plerixafor) if yes: specify…….
Was erythropoietin used? ☐ no ☐ yes

Were other drugs used for mobilisation? ☐ no ☐ yes

COMPLICATIONS
in temporal association with the donation procedure

➔ Report every serious adverse event occurring within the interval between start of the donation procedure and day 30 after the end of donation procedure with **ICD 10 Coding**
(see list in Appendix I of the manual)

Serious **A**dverse **E**vents (SAE/SAR): ☐ no ☐ yes ☐ unknown

if yes: ICD 10 Code: ___.__
Date of the SAE/SAR _____ ____ ____
yyyy mm dd
ICD 10 Code: ___.__
Date of the SAE/SAR _____ ____ ____
yyyy mm dd

REMINDER ➔ please report SAE/SAR to your National authority according to your regulations. **If donor is unrelated,** report also to **WMDA SEAR registry**

DONOR BEHAVIOUR

Would the donor donate again?
☐ no ☐ yes ☐ unknown
If no: reason: _____

☞ **Covered time interval: From the Start of the donation procedure to day 30 after completion of the procedure**

TRANSPLANT CENTER AND RECIPIENT IDENTIFICATION

Data collection is initiated by providing identification data for the recipient of the donation and the center where the transplant was performed.

EBMT CIC

Every transplant center on submitting data to the EBMT receives a Center Identification code or CIC which should be entered here. You should obtain this number or code from the transplant unit where the transplant was performed.
If you do not know the CIC of the center where the transplant was performed, leave this item blank.

EBMT database number / Unique Identification Code (UIC)

This is the number by which the EBMT Registry identifies the patient within a center. The combination of the CIC and this number renders the registration unique. You should obtain this number from the transplant unit where the transplant was performed.
If you cannot get hold of this number, leave it blank.

Center of HSCT

Write the name of the transplant center, including the hospital and the unit.

Unique patient number (UPN) or Code

Number/code used by the transplant center to uniquely identify this patient. You should obtain this number or code from the transplant unit where the transplant was performed. **This item is compulsory**.

Initials: (first name(s)_surname(s))

Write the initial of the first name of the patient followed by the initial of the surname of the patient. In countries where it is customary to do so, you can write down the initials of the first and second surname of the patient after the initial of the first name. If the local hospital guidelines or national law do not allow initials to be provided to third parties, you can write a code which has the approval of your hospital.
Make sure there is consistency in the way the identification of the patient is given so the record can always be traced even if the patient remains anonymous.

Date of birth

Correct order: year, month, day.
If you do not know the exact month: use”01” (January) as month. If the exact day is unknown: use “01”. Try to obtain exact dates as much as possible since they are crucial to identify the registration when adding follow up data.

Date of HSCT (**H**ematopoietic **S**tem **C**ell **T**ransplantation)

Date of **first** cell infusion if there are multiple infusions of one or several collected products over several days after the same conditioning regimen.

PRODUCT

BM: also includes collection of MSC mesenchymal stem cells
PBSC: peripheral collection by peripheral or central line techniques
Both: collection of BM followed by PBSC of the same donor within the same defined collection procedure (E.g. because of insufficiency of first chosen source or other circumstances, peripheral blood stem cells as well as bone marrow were collected)
Unstimulated leukapheresis: e.g. donor lymphocytes (DLI), etc.
Other: any other therapeutic cells
☞ Cord blood (umbilical cord), is **not** subject of this donor follow-up

DONOR DATA

Donor number/ID or Code

Donor identification data needed to identify donor properly.

Unrelated donor: number or code given by the donor registry
Related donor: number or code by which the donor is identified in the transplant center. If this number or code does not exist, use the relation to the recipient (mother, father, etc.).

Make sure there is consistency in the way the identification of the donor is given so the record can always be traced even if the donor remains anonymous.

Donor signed informed consent

For transmitting his/her un-identifiable data to the EBMT data base, a signed donor informed consent has to be present.

Initials: (first name(s)_surname(s))

Write the initial of the first name of the donor followed by the initial of the surname of the donor. In countries where it is customary to do so, you can write down the initials of the first and second surname of the donor after the initial of the first name. If the local hospital or donor registry guidelines or national law do not allow initials to be provided to third parties, you can write a code which has the approval of your institution.
Make sure there is consistency in the way the identification of the donor is given so the record can always be traced even if the donor remains anonymous.

Relationship to recipient

- Related donors

Syngeneic: Twins develop from a single egg (monozygotic) or two eggs (dizygotic). If the transplant is from a monozygotic twin, known as "identical twins" the transplant is defined as **syngeneic** and the histocompatibility genes in donor and patient are the same.

Identical sibling: If the patient and their donor have the same parents (but are not identical twins) and the HLA antigens are identical, it is most likely that both siblings have inherited the same copies of chromosome 6 from each parent and are therefore 'geno typically' identical, i.e.

both siblings have the same genes for the HLA antigens. This is an HLA-**identical sibling** transplant.

Other family member: *Matched*:
Occasionally other family members (parents, cousins, half siblings etc.) could also be HLA-identical to the patient but could not have inherited the same copies of chromosome 6 as the patient (because they don't share the same parents). This is defined as an HLA-**matched other family member**.
Unmatched:
The donor can also be a family member (sibling, etc.) but with different HLA antigens. That would be an HLA-**mismatched other family member**.
If other family member, describe the relation: parents, cousin, aunt, uncle, child, etc.

- Unrelated donors
When the donor has no family connection to the recipient it is called **unrelated donor**. These donors are found through an unrelated donor registry.

Date of birth

Correct order: year, month, day.
If you do not know the exact month: use"01" (January) as month. If the exact day is unknown: use "01". Try to obtain exact dates as much as possible since they are crucial to identify the registration when adding follow up data.

Sex

Indicate the gender of the donor, needed to identify the donor properly

DONATION PROCEDURE

The donation procedure consists of a series of actions. Depending on the product being collected, it can start with an injection, anesthesia, etc., and will end with the cell collection itself.

Once the procedure has been initiated, even if it were to be stopped prematurely (due to any type of reasons, associated to either the donor or the recipient), and the cells are actually never collected, the activity fulfills the definition of a donation procedure and the donor should be registered and followed.

Example: an allergic reaction after first dose of GCSF may stop the procedure; procedure may be stopped due to an incident that takes place when preparing for anesthesia or other intervention. In both scenarios, even though no cells would have been collected in either case, the donor should still be registered and followed up.

First day of this collection

-**Peripheral blood stem cells**: the first day of one or more collection days (after stimulation). If the collection lasts more than one day, please enter the first date, even if there was a problem in between.

-**Bone marrow**: the date of bone marrow harvest (date of collection is the same as start of donation procedure)
-**Non-stimulated leukapheresis**: first day of the (non-stimulated) apheresis

COLLECTION

EBMT Code (CIC)
The EBMT will provide a Centre Identification Code (CIC) to collection centers or donor registries (*) if they do not already have a membership CIC. If you do not know the CIC of the center or donor registry where the collection was performed, please contact the EBMT Registry at

registryhelpdesk@ebmt.org

(*) The CIC of a collection center that is not a member of the EBMT is for data management purposes only and does not confer any membership rights to that collection center or donor registry

Collection center
Write the full name of the center where the collection was performed, including city and country

Donor registry
Unrelated donors only:
Write the full name of the donor registry. If available, add also the BMDW/WMDA code which can be found at:

http://www.bmdw.org/index.php?id=addresses_members&no_cache=1

Contact person
Write down the name of the person who will be responsible for updating or correcting the data contained in these forms should this be necessary

Date of this report
This is the date the data for this single collection for this donor was collated or put together. If you enter the data directly from the donor notes, it is the date you are entering the data. If you fill in a paper form, it is the date you filled in the form. This date will remain unchanged regardless of how much more data (follow up) you add to this particular collection. It should not be later than 100 days after this procedure.

Start date of donation procedure
The donation procedure starts with the first injection of a mobilizing agent, the start of anesthesia or the start of apheresis (in case of non-stimulated leukapheresis, e.g. for DLI/NK or any other therapeutic cells)
-Peripheral blood stem cells: the first day of mobilizing agent injections
-**Bone marrow**: the date of bone marrow harvest (date of procedure is the same as the first date of collection)
-**Non-stimulated leukapheresis**: day of the (non-stimulated) apheresis

Chronological number of this donation procedure

It refers to the number of the donation procedure that this donor has undergone throughout his/her lifetime, including previous donations in other centers /for other recipients.
If this is not the first donation for this donor, please indicate the collection center and date of the previous donation.

For the following question, please tick Yes or No.

Collection completed

- The product collection is deemed completed when the collection center considers that the collected product is sufficient for infusion. If the procedure is interrupted before this stage has been reached, tick “No”.
-

For the next questions, indicate whether any of these products has been used in the donor.

Hematopoietic growth factors used

- Granulocyte colony-stimulating factors, GCSF, are used to mobilise haematopoietic stem cells to the peripheral blood
  e.g.: Filgrastim, Lenograstim, Pegfilgrastim, other

If growth factors have been used, provide the brand name. You can find a list of known brand names in Appendix III.

Cell binding inhibitors used

- Cell binding inhibitors also mobilise haematopoietic stem cells to the peripheral blood but work differently from G-CSF, by blocking the receptors which normally retain haematopoietic stem cells in the bone marrow. Currently the only cell binding inhibitor available is Plerixafor.

If a cell binding inhibitor has been used, provide the brand name. You can find a list of known brand names in Appendix III.

Erythropoietin used

- Erythropoietin is a hormone produced by the kidneys that stimulates the production of red blood cells by bone marrow. Some teams may administer it to boost the production of red blood cells, either for collection of autologous blood before BM donation (normally, the blood is then retransfused after the donation to decrease anaemia after BM collection) or to enhance recovery of RBC after BM collection in absence of RBC transfusion.

Other drugs used for mobilisation

- Other drugs used for mobilisation should only be answered positively if the drugs are used for actually mobilizing the cells: pain killers, etc. should not be reported here.

COMPLICATIONS
in temporal association with the donation procedure

Serious adverse event or reaction (SAE/SAR)
See definition, page 4

IMPORTANT NOTE
Only report events with WHO toxicity grade 3 and 4, or SAEs that:
1. Lead to death
2. Are life-threatening events requiring in-patient hospitalization or prolongation of existing hospitalization due to WHO grade 3 or 4 toxicity or causing to
3. Lead to persistent or significant disability/incapacity

Fill in ICD 10 code and the 1st date the event was detected.

Report the complications/SAE/SAR that are in temporal association with the donation and appear before day 30 after the donation procedure started. SAE/SAR taking place after this date should be reported with the ***Long term Follow-up report***.

IMPORTANT NOTE
Death, whether it happened before or after 30 day**s** from donation, should be reported by submitting a ***Long term follow up report*** in addition to this report.

In Appendix II A1 we have listed those ICD10 which may be more commonly associated to a donation procedure. If the complication or SEAR you want to report is not listed, you can find more codes at:

WHO International Statistical Classification of Diseases and Related Health Problems (current version 2010)

IMPORTANT NOTE

Unrelated donors: WMDA SEAR reporting

Reporting to WMDA is **mandatory for WMDA accredited registries and** highly recommended for all other registries.
Please go to WMDA website: http://www.worldmarrow.org/index.php?id=

- Click on the left side: S(P)EAR Committee How to report S(P)EAR to the WMDA for information
- Follow the link to the online reporting system:
  http://www.surveygizmo.com/s3/720793/SEAR-and-SPEAR-2012

DONOR BEHAVIOUR

This question is mandatory for WMDA accredited registries, but it is highly recommended that it be asked also of related donors.

Would the donor donate again?

- If donor does not want to donate again, write a short comment why not; e.g. age, disease

Donor outcome

Long term follow up report after last donation procedure

To be used also used when reporting the death of the donor

TRANSPLANT CENTRE AND RECIPIENT IDENTIFICATION

EBMT CIC _____
(if known)

EBMT database number _____
(if known)

Center of HSCT: _____

Hospital/unit: _____

Unique Patient Number or Code …….

Initials: _____ _____(first name(s)_surname(s))

Date of birth: _____ ____ ____
yyyy mm dd

Date of HSCT: _____ ____ ____
yyyy mm dd

COLLECTION CENTRE IDENTIFICATION

EBMT Code (CIC): …….. .....
(If known)

Collection center: …….....

Registry: …….....

…….....

Contact person: ……..……

PRODUCT

☐ BM (Including collection of MSC)
☐ PBSC
☐ Both *(*BM and PBSC)
☐ Unstimulated leukapheresis
(e.g. donor lymphocytes (DLI), etc.)
☐ other, specify _____

DONOR DATA

Donor number/ID: …….. ……

……

Initials: __ __ (first name(s)_surname(s))

Date of birth: _____ ____ ____
yyyy mm dd

Sex: ☐ male ☐ female

FOLLOW UP OR DEATH REPORT

Date of last follow up or death: _____ ____ ___
yyyy mm dd

FU Report: __ month __ year

Date of this report: _____ ____ ____
yyyy mm dd

SAE/SAR SINCE LAST REPORT

MALIGNANCY

Hematological malignancy? ☐ no ☐ yes ☐ unknown

If yes: ICD 10 Code: ___.__ (see manual, list in Appendix I)

Confirmed by medical data ☐ no ☐ yes ☐ unknown

Date of the SAE/SAR _____ ____ ____
yyyy mm dd

Non-hematological malignancy? ☐ no ☐ yes ☐ unknown

if yes: ICD 10 Code: ___.__ *(see manual, list in Appendix I)*

Confirmed by medical data ☐ no ☐ yes ☐ unknown

Date of the SAE/SAR _____ ____ ____
yyyy mm dd

NON MALIGNANCY

Autoimmune disease? ☐ no ☐ yes ☐ unknown

if yes: ICD 10 Code: ___.__ *(see manual, list in Appendix I)*

Confirmed by medical data ☐ no ☐ yes ☐ unknown

Date of the SAE/SAR _____ ____ ____
yyyy mm dd

REMINDER ➔ please report SAE/SAR to your National authority according to your regulations. **If donor is unrelated,** report also to **WMDA SEAR registry**

DONOR STATUS ON THIS DATE

☐ Alive

☐ Dead: Donation related ☐ no ☐ yes ☐ unknown

ICD 10 code for main cause of death: ___.__
(Select only one main cause)
ICD 10 code(s) for contributory causes of death:
___.__ ___.__ ___.__
(See manual: list of ICD 10 codes in Appendix I)

Describe below the cause of death if necessary:
……

☐ Check here if donor lost to follow up

DONOR BEHAVIOUR

Would the donor donate again?
☐ no ☐ yes ☐ unknown

If no: reason: _____

COLLECTION CENTER IDENTIFICATION
PRODUCT
DONOR DATA
See above for definitions. These data are used to retrieve the correct donor registration when adding the follow up.

LONG TERM FOLLOW UP REPORT

Date of last follow up or death.

This should be the last date the donor was known to be alive. This can have been ascertained by phone, email or letter.

If the donor has died, it should be the date of death

Date of this report

This is the date in which you collated or put together the last set of data you are about to enter. If you fill in a paper follow up form, for example, it would be the date you filled in the form.

SAE/SAR SINCE LAST REPORT

In APPENDIX l we have listed those ICD10 referring to Malignancies and Autoimmune diseases which may be more commonly used. If the malignancy or disease you want to report is not listed, you can find more codes at:

WHO International Statistical Classification of Diseases and Related Health Problems (current version 2010)

Hematological malignancy

Indicate any hematological malignancy that has been diagnosed during the period covered by this report.

Certainty of the diagnosis needs to be confirmed. For example, does the information come only from the donor telling you that he had a malignancy or autoimmune disease (”unconfirmed”) or is there a medical report, a histology result or a serological result which confirms the diagnosis (“diagnosis confirmed by medical data”).

Please report with ICD Code, see list in Appendix l A2:

Non-hematological malignancy

Indicate any non-hematological malignancy that has been diagnosed during the period covered by this report.

Regarding the certainty of the diagnosis, see above.

Please report with ICD Code, see list in Appendix l A2:

Autoimmune disease

Indicate any autoimmune disease that has been diagnosed during the period covered by this report.

Regarding the certainty of the diagnosis, see above.
Please report with ICD Code, see list in Appendix l A3:

UNRELATED DONORS: Report to WMDA SEAR registry, see page 13

DONOR STATUS AT THIS DATE

Death

The information on cause of death is very important. We ask that you indicate whether the death is considered donation related or not. This is of course difficult to gauge, particularly when the interval between donation and death is long, and will be only used as an indication.

Report one major cause of death using its ICD code where possible. In addition, you can indicate as many causes as are considered to have been contributory to the outcome. The use of ICD codes is preferable although you can also add a description if necessary.

Lost to follow-up

When indicating lost to follow up, the date of last contact should be the last date that it is known for sure the donor was alive. Should only be used if:
- any contact with the donor has been lost (follow the guidelines of your center on how many attempts to contact the donor have to be done for this status to be acceptable).
- the donor refused to be followed up.

DONOR BEHAVIOUR
See above

APPENDIX I

A1: Selection of SAE during donation procedure

➔ The list of course is not considered complete and every effort to prevent underreporting should be made

Serious adverse event	Linked ICD code with main description	

- ***Vascular events, bleeding, thrombosis***

Angina pectoris	I20	**Angina pectoris**
Acute myocardial infarction	I21	**Acute myocardial infarction**
Arterial thromboembolism	I74	Arterial **embolism and thrombosis**
Venous thromboembolism	I80	**Phlebitis, thrombophlebitis**
Portal vein thrombosis	I81	**Portal vein** thrombosis
Other	I82	**Other venous embolism and thrombosis**
Pulmonary embolism PE	I26	Pulmonary embolism
Subarachnoid haemorrhage	I60	**Subarachnoid haemorrhage** (incl. ruptured cerebral aneurysm)
Intracranial bleeding	I61	**Intracerebral hemorrhage**
Other Intracranial bleeding	I62	**Other non traumatic** intracranial hemorrhage
Cerebral infarction	I63	**Cerebral infarction**
Stroke	I64	**Stroke, not specified as hemorrhage or infarction**
Transient cerebral ischaemic attack	G45	**Transient cerebral ischaemic attack** and related syndroms

- ***Other cardiac events***

Arrhythmia	I44	**Atrioventricular and left bundle-branch block**
Arrhythmia	I45	**Other conduction disorders**
Cardiac arrest	I46	**Cardiac arrest**
Arrhythmia	I47	**Paroxysmal tachycardia**
Arrhythmia	I48	**Atrial fibrillation and flutter**
Arrhythmia	I49	**Other cardiac arrhythmias**

- ***Other cerebral events***

Seizures	G40	**Epilepsy**
Seizures	R56.8	**Other and unspecified convulsions**

- ***Pulmonary events***

Respiratory arrest	R09.2	**Respiratory arrest**
Aspiration pneumonia	J69	**Pneumonitis due to** solids and liquids**,** Aspiration pneumonia
Pulmonary edema "White lung disease"	J81	**Pulmonary edema** Acute **edema of lung,** pulmonary congestion
ALI Acute Lung Injury	J80	**Adult respiratory distress syndrome**
TRALI Transfusion Related Acute Lung Injury	T80	**Complication following infusion, transfusion and therapeutic injection, incl. transfusion reaction**
Transient respiratory disturbance	R06	**Abnormalities of breathing**
Capillary leak of lung etc.	R60.9	**Oedema, unspecified** fluid retention NOS

- ***Catheter related complication***

Pneumothorax	J93	**Pneumothorax**
Heavy bleeding from exit site	T81.0	**Haemorrhage and haematoma complicating a procedure, not elsewhere classified** haemorrhage at any site resulting from a procedure

Accidental perforation of blood vessel, nerve, organ	T81.2	**Accidental puncture and laceration during a procedure, not elsewhere classified**
Haematothorax	J94.2	**Haematothorax** Haematopneumothorax

- ***Anesthesia related***

Malignant hyperthermia	T88.3	**Malignant hyperthermia due to anaesthesia**

- ***Others***

Anaphylaxis	T78.2	**Anaphylactic/allergic shock**, allergic anaphylactic reaction
Serious infection	A41.9	**Sepsis, Septicaemia, unspecified, septic shock**
Serious arterial hypertension	I10	**Essential (primary) hypertension,** high blood pressure
Splenic rupture	D73.5	**Infarction of spleen** Splenic rupture, nontraumatic
Sickle cell crisis	D57.0	**Sickle-cell anaemia with crisis**
Triggering, flare-up or exacerbation of inflammatory or Autoimmune disease	M35.9	**Systemic involvement of connective tissue, unspecified** Autoimmune disease (systemic) **not elsewhere classified** Collagen (vascular) disease **not elsewhere classified**

A2: Selection of malignancies to be recorded during long term follow-up

➔ This list is not considered complete and every effort to prevent underreporting should be made.

Haematological malignancies	Linked ICD code with main description	
Hodgkin lymphoma	C81	Hodgkin lymphoma
Follicular lymphoma	C82	Follicular lymphoma
Small cell B-cell lymphoma	C83.0	Lymphoplasmacytic lymphoma, Nodal marginal zone lymphoma Non-leukaemic variant of B-CLL, Splenic marginal zone lymphoma
Mantle cell lymphoma	C83.1	Centrocytic lymphoma Malignant lymphomatous polyposis
Diffuse large B-cell lymphoma	C83.3	Diffuse large B-cell lymphoma T-cell rich B-cell lymphoma
Lymphoblastic (diffuse) lymphoma	C83.5	B-precursor lymphoma Lymphoblastic B-cell lymphoma, Lymphoblastic lymphoma NOS Lymphoblastic T-cell lymphoma, T-precursor lymphoma
Burkitt lymphoma	C83.7	Atypical Burkitt lymphoma “Burkitt-like” lymphoma
Other non-follicular lymphoma	C83.8	Primary effusion B-cell lymphoma Intravascular large B-cell lymphoma Lymphoid granulomatosis
Non-Hodgkin lymphoma	C83.9	Non-follicular (diffuse non-Hodgkin lymphoma), unspecified
T-cell lymphoma	C84	Mature T/NK-cell lymphomas
Other non-Hodgkin lymphoma	C85	Other and unspecified types of non-Hodgkin lymphoma
Large B-cell lymphoma	C85.2	Mediastinal (thymic) large B-cell lymphoma
Other T/NK-cell Lymphoma	C86	Other specified types of T/NK-cell Lymphoma
Other B-cell lymphoma	C88	Other B-cell lymphoma[malignant immunoproliferative diseases]
Waldenström	C88.0	Waldenström macroglobulinaemia
Other heavy chain disease	C88.2	Franklin disease, Gamma heavy chain disease, Mu (μ) heavy chain disease
Immunoproliferative small intestinal disease	C88.3	Alpha heavy chain disease, Mediterranean lymphoma
Extranodal marginal zone B-cell lymphoma	C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lyphoma]
Malignant immunoproliferative disease	C88.9	Immunoproliferative disease NOS
Multiple myeloma	C90	Multiple myeloma and malignant plasma cell neoplasms
Acute lymphoblastic leukaemia	C91.0	Acute lymphoblastic leukaemia (ALL)
Chronic lymphocytic leukaemia	C91.1	Chronic lymphocytic leukaemia of B-cell type
Prolymphocytic leukaemia	C91.3	Prolymphocytic leukaemia of B-cell type
Hairy-cell leukaemia	C91.4	Hairy-cell leukaemia, incl. Leukaemic reticuloendotheliosis
T-cell lymphoma/leukaemia adult	C91.5	Adult T-cell lymphoma/leukaemia, (HTLV-1-associated)
Prolymphocytic leukaemia	C91.6	Prolymphocytic leukaemia of T-cell type
Other lymphoid leukaemia	C91.7	Incl. T-cell large granular lymphocytic leukaemia

Haematological malignancies	Linked ICD code with main description	
Mature B-cell leukaemia	C91.8	Mature B-cell leukaemia Burkitt-type
Lymphoid leukaemia	C91.9	unspecified
Acute myeloblastic leukaemia	C92.0	Acute myeloblastic leukaemia, (AML)
Chronic myeloid leukaemia	C92.1	Chronic myeloid leukaemia (CML)
Atypical chronic myeloid leukaemia	C92.2	Atypical chronic myeloid leukaemia
Myeloid sarcoma	C92.3	Myeloid sarcoma, incl. Chloroma, Granulocytic sarcoma
Acute promyelocytic leukaemia	C92.4	Acute promyelocytic leukaemia (PML)
Acute myelomonocytic leukaemia	C92.5	Acute myelomonocytic leukaemia
Acute myeloid leukaemia	C92.6	AML with 11q23- abnormality
Other myeloid leukaemia	C92.7	Other myeloid leukaemia
Acute myeloid leukaemia with	C92.8	Acute myeloid leukaemia with multilineage dysplasia
Myeloid leukaemia, unspecified	C92.9	unspecified
Acute monoblastic/monocytic leukaemia	C93.0	Incl. AML M5a, AML M5b, AML M5
Chronic myelomonocytic leukaemia	C93.1	Incl. Chronic monocytic leukaemia, CMML 1/2/with eosinophilia
Juvenile myelomonocytic leukaemia	C93.3	Juvenile myelomonocytic leukaemia
Other monocytic leukaemia	C93.7	Other monocytic leukaemia
Monocytic leukaemia	C93.9	unspecified
Acute erythroid leukaemia	C94.0	Acute erythroid leukaemia, incl. AML M6 (a)(b)
Acute megakaryoblastic leukaemia	C94.2	Acute megakaryoblastic leukaemia incl. AML M7
Mast cell leukaemia	C94.3	Mast cell leukaemia
Acute panmyelosis with myelofibrosis	C94.4	Acute panmyelosis, incl. acute myelofibrosis
Myelodysplastic/myeloproliferative disease	C94.6	not classified
Other specified leukaemias	C94.7	Incl. Aggressive NK-cell/ Acute basophilic leukaemia
Acute leukaemia of unspecified cell type	C95.0	Acute leukaemia of unspecified cell type
Chronic leukaemia of unspecified cell type	C95.1	Chronic leukaemia of unspecified cell type
Other leukaemia of unspecified cell type	C95.7	Other leukaemia of unspecified cell type
Leukaemia, unspecified	C95.9	Leukaemia, unspecified
Neoplasms of lymphoid, haematopoietic and related tissue	C96	Other and unspecified malignant neoplasms

Non haematological malignancies	Linked ICD code with main description	
➔ ***Malignant neoplasm of:***		
Bladder	C67	Bladder
Breast	C50	Breast
Colon and rectum	C18 C19 C20	Colon Rectosigmoid junction Rectum
Corpus *uteri*	C54	Corpus uteri
Kidney	C64	Kidney, except renal pelvis
Lung	C34	Bronchus or lung
Melanoma of skin	C43	Malignant melanoma of skin
Oral cavity and pharynx	C10 C11 C12 C13 C14	Oropharynx Nasopharynx Piriform sinus Hypopharynx Of other and ill-defined sites in the lip, oral cavity and pharynx
Ovary	C56	Ovary
Prostate	C61	Prostate
Stomach	C16	Stomach

A3: Selection of autoimmune disorders to be recorded during long term follow-up

➔ The list of course is not considered complete and every effort to prevent underreporting should be made

Autoimmune disorder	Linked ICD code with main description	
Evans syndrome	D69.3	**Idiopathic thrombocytopenic purpura** Evans' syndrome
Immune thrombocytopenia	D69.6	**Thrombocytopenia, unspecified**
Graves disease Hashimoto thyroiditis	E05.0 E06.3	**Thyrotoxicosis with diffuse goitre** Exophthalmic or toxic goiter NOS Graves' disease, toxic diffuse goitre **Autoimmune thyroiditis** Hashimoto's thyroiditis
Rheumatoid arthritis	M05	**Rheumatoid arthritis**
	M06	**Other rheumatoid arthritis**
Still disease	M06.1	**Adult-onset still's disease**
Systemic lupus erythematosus	M32	**Systemic lupus erythematosus**
Antiphospholipid antibody syndrome	D68.6	**Other thrombophilia,** Anticardiolipin syndrome, Presence of the lupus anticoagulant
Scleroderma	M34 L94	Systemic sclerosis Other localized connective tissue disorders
Dermatopolymyositis	M33	**Dermatomyositis**
Dermatomyositis	M33.1	**Other** dermatomyositis
Inflammatory myopathies	M33.2	**Polymyositis**
Mixed connective tissue disease	M35.1	**Other overlap syndromes**
Sjögren's syndrome	M35.0	**Sicca syndrome [Sjögren]**
Vasculitis syndromes	L95	**Vasculitis limited to skin, NOS**
Vasculopathies	M31	**Other necrotizing vasculopathies**
Hypersensitivity angiitis	M31.0	**Goodpasture syndrome**
Thrombotic microangiopathy	M31.1	**Thrombotic thrombocytopenic purpura**
Wegener granulomatosis	M31.3	**Necrotizing respiratory granulomatosis**
Ankylosing	M45	**Ankylosing spondylitis side unspecified**
Inflammatory bowel disease: Crohn's disease Colitis ulcerosa	 K50 K51	 **Crohn's disease,** **Ulcerative colitis**
Iridocyclitis	H20	**Iridocyclitis**

APPENDIX ll

Abbreviations

BM	Bone Marrow
CIC	Center identification code
DL	Donor lymphocytes
DLI	Donor lymphocytes infusion
EBMT	European Group for Blood and Marrow Transplantation
GCSF	Granulocyte colony-stimulating factor
HLA	Human lymphocyte antigen
HPCA	Haematopoietic stems cells apheresis
HSC	Haematopoietic stems cells
HSCT	Haematopoietic stems cells transplantation
ICD	International Statistical Classification of Diseases
MSC	Mesenchymal stem cells
NK	Natural killer cells
PBSC	Peripheral blood stem cells
SAE	Serious adverse event
UIC	Unique identical code
UPN	Unique Patient Number
WBMT	Worldwide network for blood and marrow transplantation
WHO	World Health Organization
WMDA	World Marrow Donor Association

APPENDIX III

Hematopoietic growth factors

Growth factor type	Brand name
Filgrastim (G-CSF)	**Neupogen**
	Nivestim
	Ratiograstim
	Tevagastrim
	Zarzio
Lenograstim (G-CSF)	**Granocyte**
	Euprotin
	Myelostim
Pegfilgrastim (G-CSF, pegylated)	**Neulasta**
	Neupopeg
	Neulastim

Cell binding inhibitors

Cell binding inhibitor type	Brand name
Plerixafor	**Mozobil**

APPENDIX IV

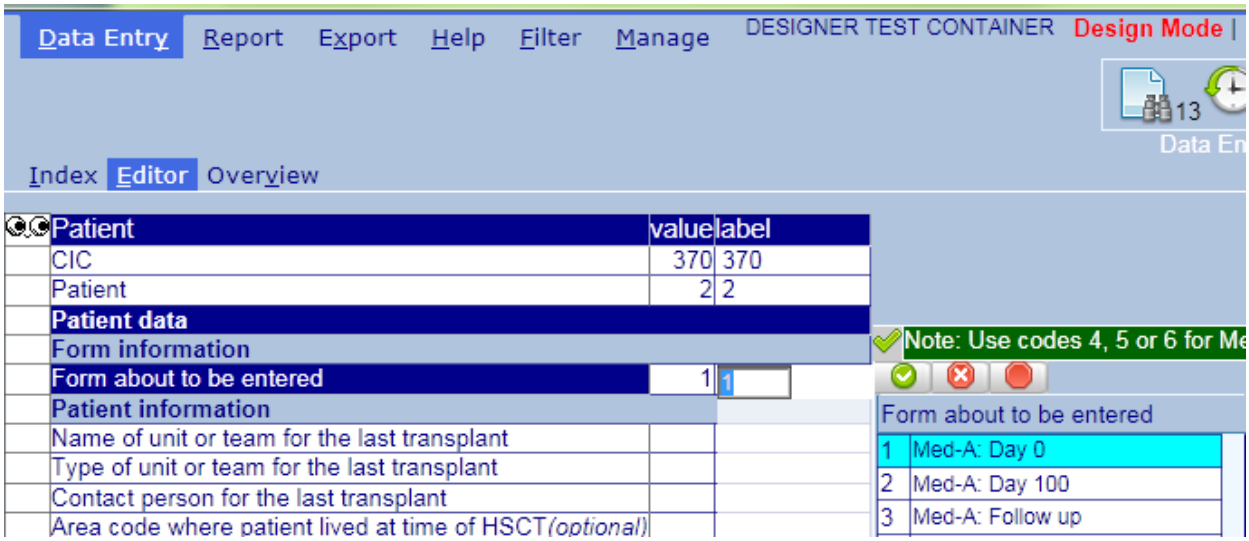
How to create a dummy patient in ProMISe if donor outcome data cannot be linked to the recipient registration

Whenever possible, it is strongly recommended that the donor data be attached to the recipient (patient) registration. However, this is not possible if the donor is unrelated and has not given consent for the transplant centre to see their data. In those cases, a dummy recipient needs to be created in order to be able to enter the donor data.

Here we present step-by-step instructions on how to create the dummy patient. Note that these instructions are for existing users of the system who already have some experience or training in ProMISe and are familiar with data entry.

The dummy patient needs to be created within the CIC of your institution (see page 11). The database number for the patient can be any number according to your numbering strategy.

In the first field "Form about to be entered": we recommend you use code 1 because the navigation will take you through a reduced selection of MED-A questions. (This form code is normally used for registration of HSCT on day 0):



Enter the Name of Unit or Type of Unit for your team if necessary.

Contact person: Enter the person responsible for data queries

Date of the 1st report: as it is a dummy you can enter today's date. (Shortcut key = !)

Press [Tab] or [Enter] until you reach the UPN field:

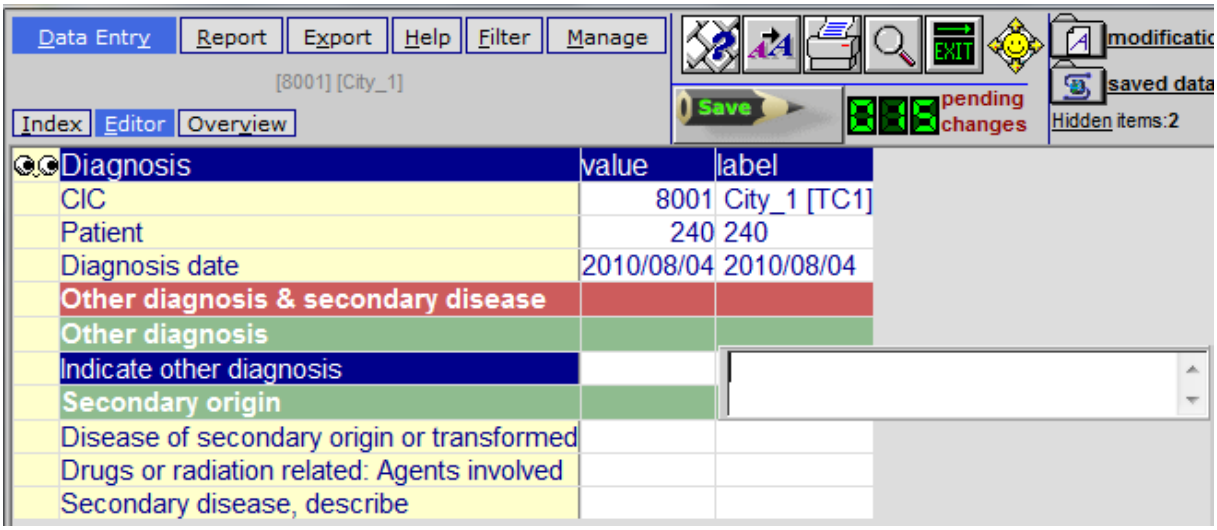
Patient information		
Centre identification for transplant/therapy	8001	City_1 [TC1]
Name of unit or team		
Type of unit or team	5	Allograft
Contact person	Me	Me
Area code where patient lived at time of HSCT*(optional)*		
Date of the 1st report	2012/09/27	2012/09/27
Date of the last report		
CRID *optional*		
Patient in nat / international study / trial		
UPN	dummy 12345	dummy 12345
Initial(s) first name	H	H
Initial(s) family name	B	B
Date of birth of the patient	1952/07/03	1952/07/03
Sex of the patient	1	Male

UPN = dummy plus the Donor registration number (enter ”dummy” to show that this patient is excluded from any data analysis, since this is not a true HSCT report). You MUST add a unique reference after the word Dummy because all UPNs should be unique in your organisation. (Automatic checks for duplicate UPNs will show as errors during Data Entry). *Note you will also need to specifically code the patient as “excluded from analysis” at a later stage in the dummy entry.*

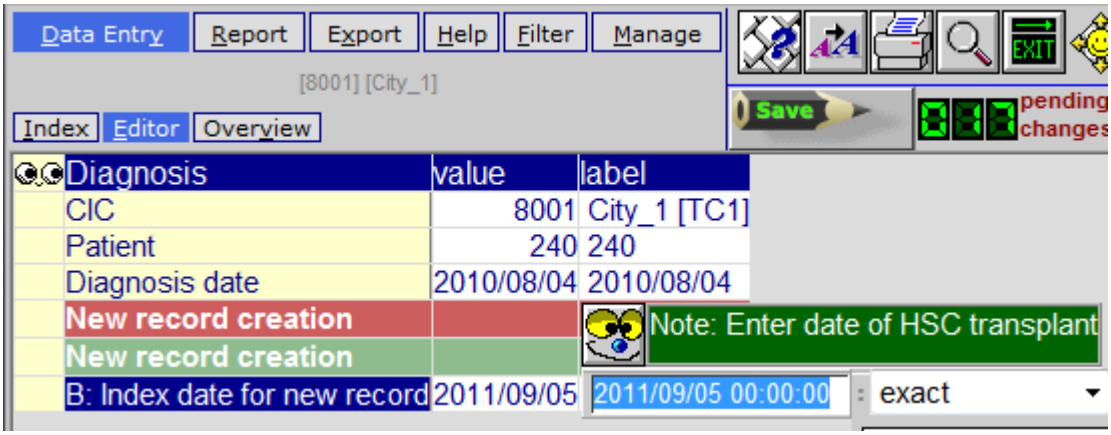
Enter the Initials, date of birth and sex of the patient if available

Next you will be asked to enter a date of diagnosis to continue with the record creation. Enter the date if known, otherwise enter a fictional date (ensuring it is after the date of birth but before the date of transplant so you do not receive validation errors).

Enter the diagnosis classification if known, otherwise select code “99 : Unknown”, press [Tab] to leave the “Indicate Other diagnosis” field blank, and continue:

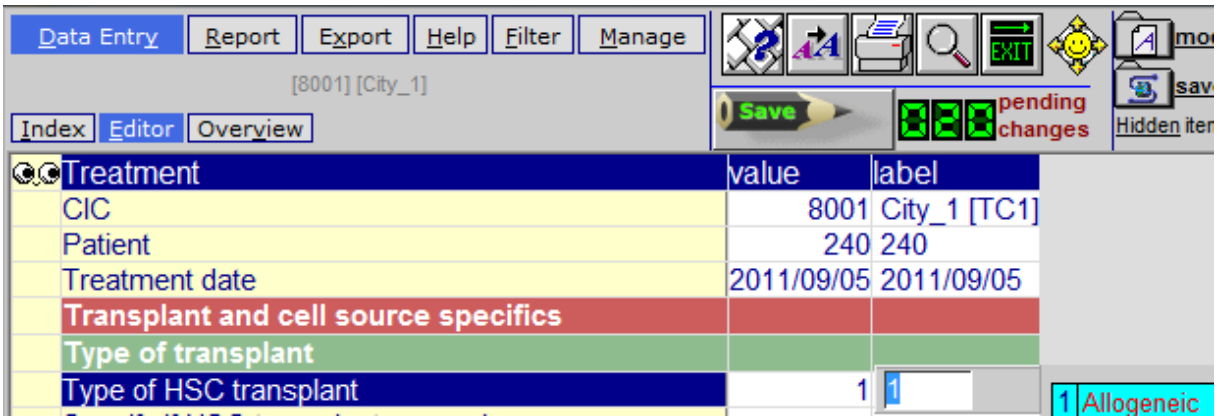


Enter the date of HSCT:

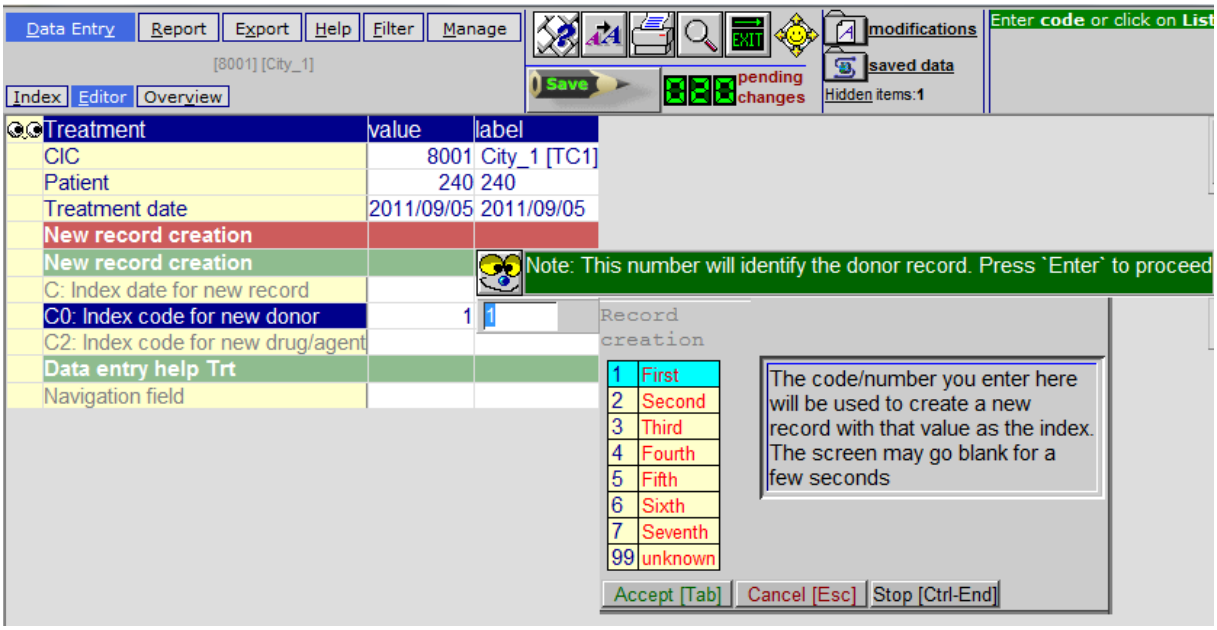


Press [Tab] or [Enter] to leave the subsequent fields blank and continue until you reach the field "Type of HSC Transplant".

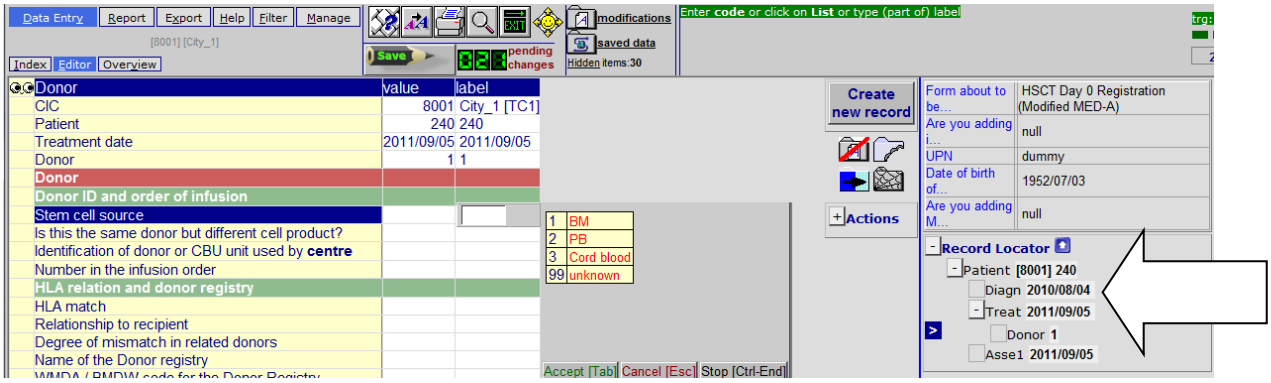
Select "Allogeneic":



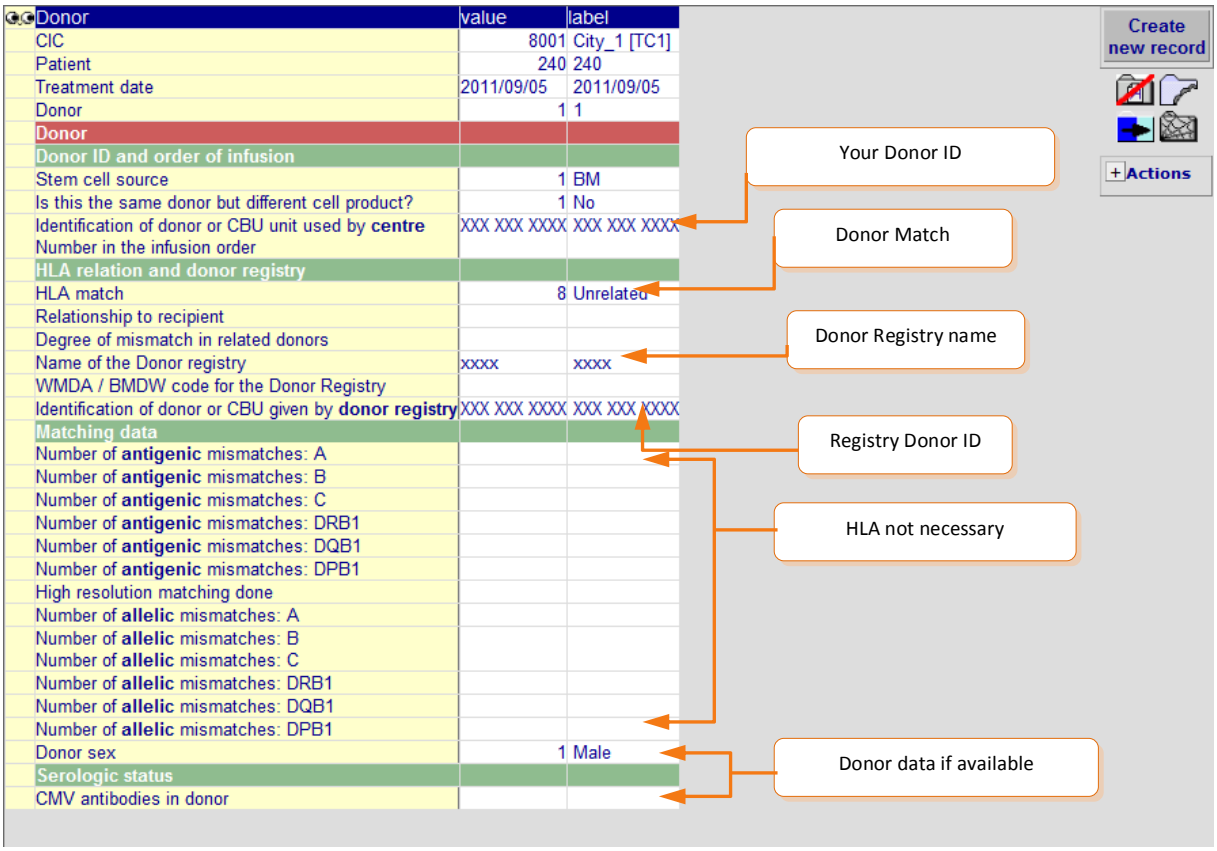
Leave the CMV Status of the patient blank, and answer Yes if there were multiple donors, otherwise answer No and press [Tab] or [Enter] to continue. You will be asked to create the Donor record. Select '`1:First`' to enter data for a single donor. (In the case of multiple donors, you will eventually be asked to create Donor record 2 and so on):



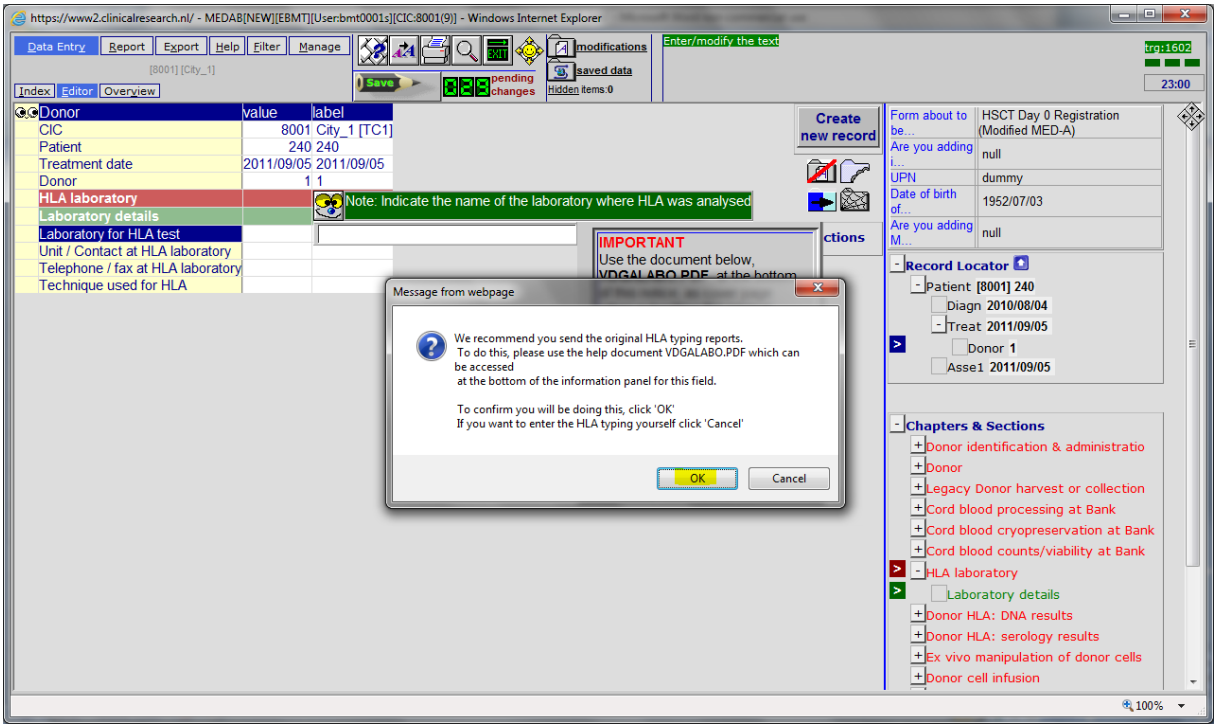
Your Record Locator on the right hand side should now show that the following records have been created: Patient, Diagn, Treat, Donor and an Assessment (Asse1) record with the same date as HSCT:



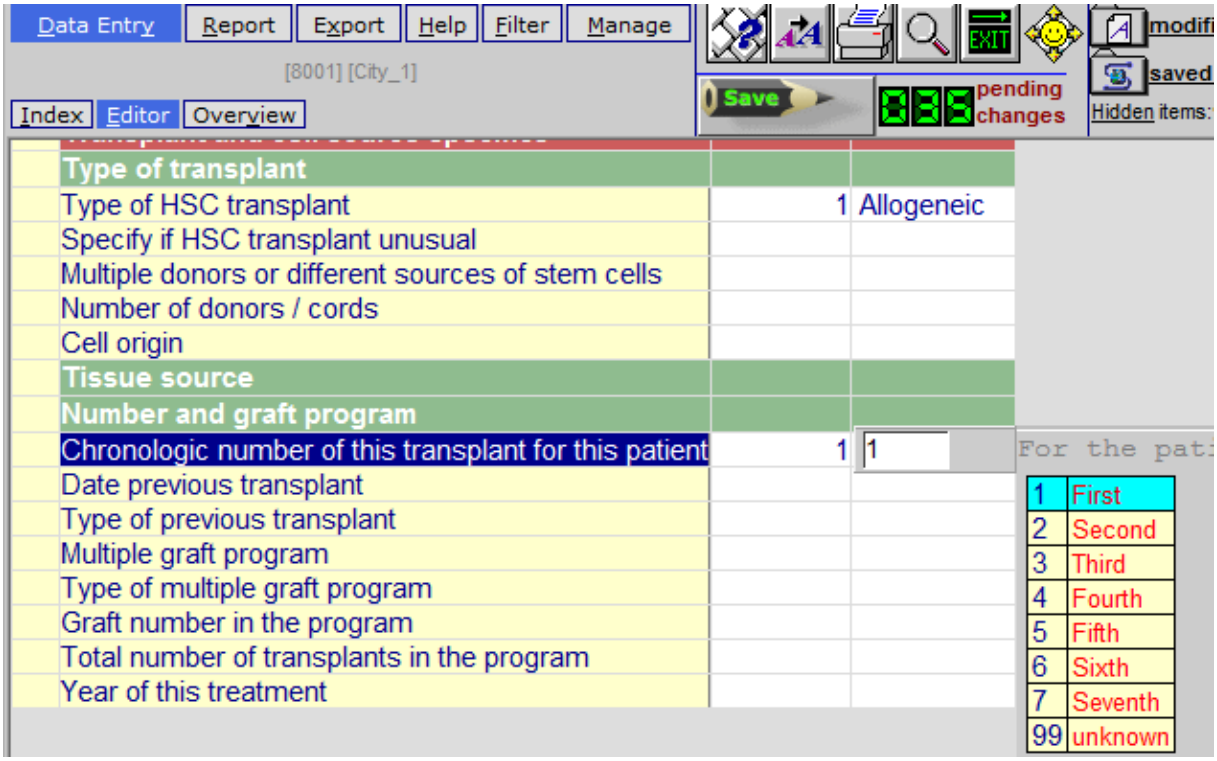
Finish completing the Donor section (example below):



Press [Tab] or [Enter] to leave the remaining fields blank and continue. When you receive the prompt regarding submission of HLA typing, press [ok] to continue:

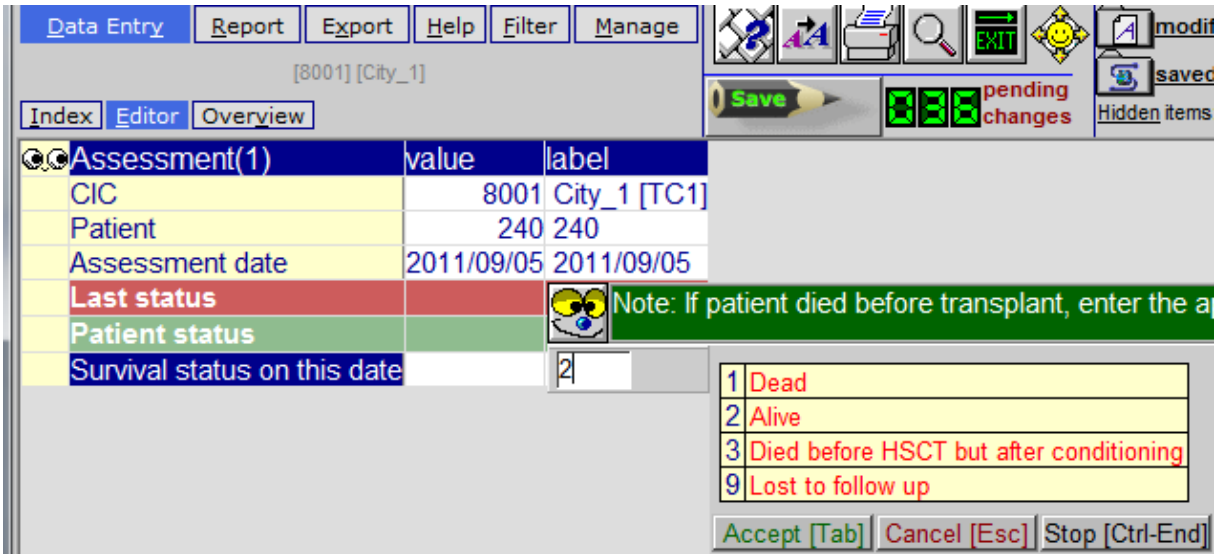


Enter the Chronological Number of the Transplant for this patient:



The next questions on conditioning and GvHD prevention drugs can be left blank.

Enter survival status (at date of HSCT):



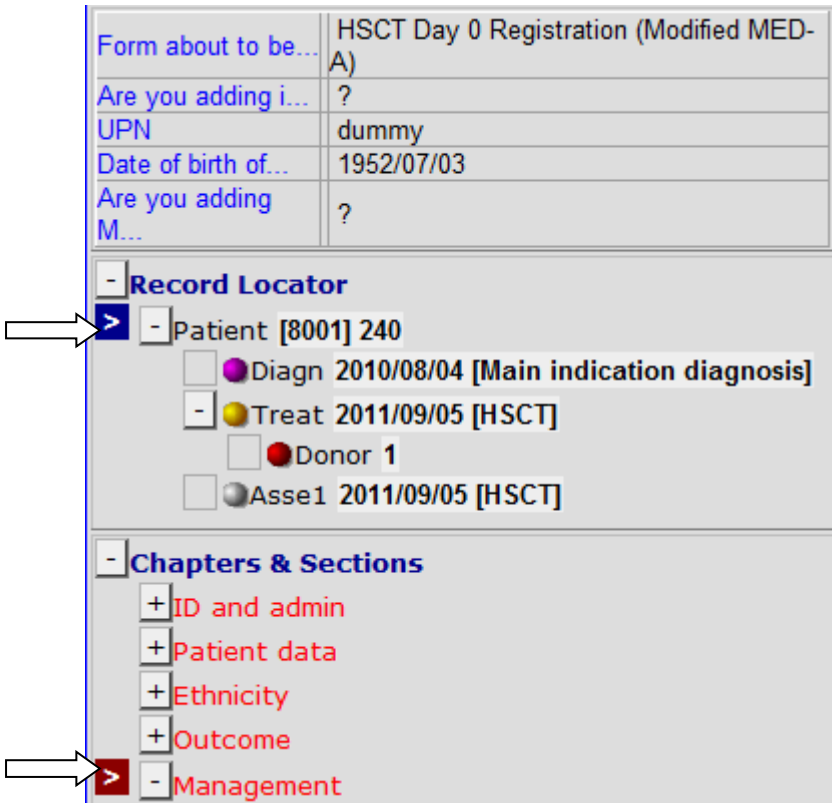
Press [Tab] to skip the Comments fields. Then click [ok] and [**SAVE**]

Finally, it is important to hide this patient registration from any analysis, as the valid registration will have been entered by the responsible transplant centre:

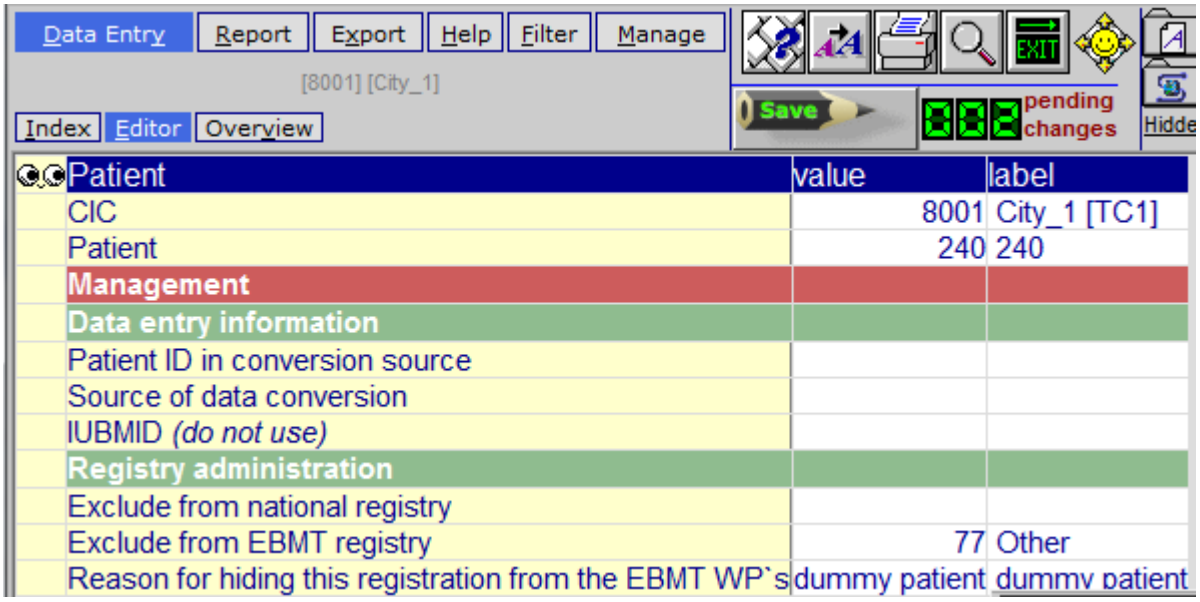
Go to the Record Locator

Record: Patient

Chapter: Management



- In “Exclude from EBMT Registry”, select code “77:Other”
- In “Reason for hiding this registration from the EBMT WP”: enter “dummy patient”:



[SAVE]

Use shortcut [Ctrl-Home] to return to the first field “Form about to be entered” where you can overwrite code 1 with code 7 and begin your Donor Outcome registration using this dummy patient:

APPENDIX V

Tips and tricks on following donors

Following up donors may be difficult in some cases. Use of Email, short message services (SMS), new media and social network facilities may help to maintain contact with donors, decreasing the number of donors lost to follow up and ensuring adequate data capturing.

APPENDIX VI

Donor Consent Templates

Find below a copy of the informed consent form used by the Swiss Donor Registry that could be used as template to produce consent forms for other institutions.

Informed consent for forwarding data to EBMT

FAMILY NAME: .....FIRST NAME: .....

In accordance with the Swiss transplantation act and its ordinances, in force since 1 July 2007, all donors in Switzerland who have donated either bone marrow or peripheral blood stem cells shall be followed up periodically. Various, unidentifiable data from the questionnaires of all donors must be collected for later evaluation. This data can be inspected and checked by the Federal Office of Public Health (FOPH). All authorised persons are under professional discretion.

We would like to report some of this information to an international register. This is the transplantation register of the 'European Society for Blood and Marrow Transplantation' (EBMT). This information can only be accessed by medical experts and employees of this register, all of whom are under professional discretion.

I herewith confirm that I have been informed of the aims of the data collection and that I was able to ask any question. I consent to my anonymized data being forwarded to the EBMT register (please tick where appropriate):

☐ YES ☐ NO

Place, date: .....

Signature of the donor: .....

Responsible doctor (block capitals): .....

(Family name and first name)

Signature of the responsible doctor: .....

Einverständniserklärung zur Weiterleitung der Daten an die EBMT

NAME: ..... **VORNAME:** .....

Gemäss dem Transplantationsgesetz und seinen Verordnungen, ab 1. Juli 2007 in Kraft, müssen in der Schweiz alle SpenderInnen, welche entweder Knochenmark oder periphere Blutstammzellen gespendet haben, regelmässig lebenslang nachkontrolliert werden. Diverse nicht identifizierbare Daten der Fragebogen aller SpenderInnen müssen zur späteren Auswertung gesammelt werden. Diese Daten können vom Bundesamt für Gesundheit eingesehen und überprüft werden. Alle autorisierten Personen unterstehen der Schweigepflicht.

Wir möchten einen Teil dieser Informationen an ein internationales Register melden. Es handelt sich dabei um das Transplantationsregister der „European Society for Blood and Marrow Transplantation“ (EBMT). Diese Informationen sind nur für medizinische Fachpersonen und Angestellte dieses Registers zugänglich, welche alle der Schweigepflicht unterstehen.

Ich bestätige, dass ich über die Ziele der Datensammlung informiert wurde und dass ich alle Fragen stellen konnte. Ich bin einverstanden, dass meine nicht identifizierbaren Daten an das EBMT-Register weitergeleitet werden (bitte entsprechendes Feld ankreuzen):

☐ JA ☐ NEIN

Ort, Datum: .....

Unterschrift des Spenders: .....

Zuständiger Arzt (Blockschrift):.....
(Name und Vorname)

Unterschrift des zuständigen Arztes: .....

Déclaration de consentement à la transmission de données à l'EBMT

NOM: ..... **PRÉNOM:** .....

Conformément à la loi sur la transplantation, en vigueur dès le 1er juillet 2007 et à ses ordonnances d'application, tous les donneurs en Suisse, que ce soit de moelle osseuse ou de cellules souches du sang périphérique, doivent subir des examens de contrôle réguliers et à vie. Un certain nombre de données sur le suivi, rendues non identifiables, doivent être collectées en vue d'une évaluation ultérieure, et ce pour tous les donneurs. Ces données peuvent être consultées et vérifiées par l'Office fédéral de la santé publique. Enfin, toutes les personnes habilitées à consulter ces données sont tenues au secret de fonction.

Nous souhaiterions transmettre une partie de ces informations à un registre international, en l'occurrence le registre sur les transplantations du « European Society for Blood and Marrow Transplantation » (EBMT). Ces informations ne sont accessibles qu'aux professionnels de la santé et au personnel de ce registre, eux aussi tenus au secret de fonction.

Je confirme avoir été informé/e des objectifs de la collecte de données et avoir pu poser toutes les questions voulues. J'accepte que mes données, rendues non identifiables, soient transmises au registre de l'EBMT (prière de cocher la case qui convient) :

☐ OUI ☐ NON

Lieu, date: .....

Signature du donneur: .....

Médecin compétent (majuscules): .....
(nom et prénom)

Signature du médecin compétent: .....

Dichiarazione d'assenso all'invio dei dati all'EBMT

COGNOME: . ..... **NOME:** .....

A norma della legge sui trapianti e le relative ordinanze applicative, in vigore a partire dal primo luglio 2007, in Svizzera tutti i donatori di midollo osseo o di cellule staminali del sangue periferico devono essere sottoposti a controlli successivi regolari e per tutta la vita. Diversi dati dei questionari destinati ai donatori e resi non identificabili sono raccolti per una valutazione successiva. Tali dati possono essere esaminati e controllati dall'Ufficio federale della sanità pubblica. Tutte le persone autorizzate alla consultazione sono tenute al rispetto del segreto professionale.

Vorremmo inviare una parte di queste informazioni ad un registro internazionale preposto ai trapianti, lo "European Society for Blood and Marrow Transplantation" (EBMT). Le informazioni sono accessibili esclusivamente al personale medico e al personale del registro europeo, tenuti al segreto professionale.

Confermo di essere stato informato in merito agli obiettivi perseguiti con la raccolta dei dati e di aver avuto modo di porre le domande che ritengo opportune. Acconsento che i miei dati, resi non identificabili, vengano inviati al registro EBMT (per favore apporre una crocetta nel riquadro corrispondente):

☐ SI ☐ NO

Luogo e data: .....

Firma del donatore: .....

Medico competente (in stampatello): .....
(cognome e nome)

Firma del medico competente: .....