

## FAQ:

1. What should we enter in the field "Date of infusion" if it is empty?

The field "Date of infusion" is filled automatically by DKMS if the product has been cryopreserved and a transfusion date has been reported to DKMS.

2. What is the difference between the two engraftment options (ANC and checkbox engrafted + date/ ANC or PLT)?

Referring to the EBMT handbook (<https://www.ebmt.org/education/ebmt-handbook> (no 41.1)) this means that different engraftment types can occur at different times, therefore we ask for the different values.

3. Can a severe adverse event relating to the stem cell product and/or recipient occur (minimum 3 month after the donation)?

Responsibility for reporting SPEARs is with the TC. It has been discussed in the WMDA group intensively and it was consent that there should be a hint on the form if a SPEAR had happened and if yes, if it was reported. If not relevant, it can be left out. This question is not new, it has been on the forms in the past as well.

4. Why do we have questions about the dates of transfusion, cryopreservation and significant adverse reactions on our annual Patient update?

This information is really important for us and in case we haven't received the first update, we want to make sure to receive the information at a later point. If this information has already been given, the questions can be ignored.

5. What should we do if our SPAM program did not accept your attachment?

There is nothing we and our IT can do about this, it is due to the settings of your SPAM filters, so we kindly ask you to adjust them. If you need further support please feel free to get in contact with us.

6. Patient name

Due to the data minimization required by DSGVO resp. GDPR, WMDA and DKMS decided to dispense with the patient name in the form and to exclusively communicate via the patient and donor numbers. Several transplant centers had in the past reported that they would no longer accept patient names on the forms. We understand that the missing name may currently mean additional work for some transplant centers, especially if there is no technical link between patient number and name. We would therefore like to suggest that you have a query option implemented, e.g. by your IT.

We would like to inform you that until further notice we will include the patient's name in the e-mail so that you can assign the patient more easily.

7. Patient consent

Forms released August 2022, there was an option to provide information about patient consent for data sharing with donors. This led to reasonable queries. We have therefore re-examined the matter of patient consent with our legal department: As long as only anonymous information without personal information/identifying information about the patient is forwarded to a donor, this does not fall under the GDPR or the applicable national data protection regulations and consequently does not require patient consent. This has also been confirmed by EBMT. However, the patient must be informed that his or her data will be shared with "third

parties", i.e. the donor center and collection clinics (a prerequisite for JACIE accreditation), but this consent is already given as part of the EBMT patient consent, since sharing of information with clinical institutions includes donor centers/collection clinics. EBMT has confirmed this and will include some additional information on its website. It is therefore not necessary to introduce separate consent forms.

Based on this, we have adjusted the section in our forms as follows:

First Patient Update Form:

<p><b>Recipient data can not be shared with the donor due to:</b></p> <p><input type="checkbox"/> Restrictions</p> <p>Outcome data will be shared with the Collection Center in accordance with JACIE Accreditation. Anonymous and non-identifiable information is forwarded to the donor. Recipients do not have to explicitly consent according to Data protection laws (i.e. GDPR).</p>
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Yearly Patient Update Form:

<p><b>Recipient data can not be shared with the donor due to:</b></p> <p><input type="checkbox"/> Restrictions</p> <p><input type="checkbox"/> Patient is lost to follow-up</p> <p>Anonymous and non-identifiable information is forwarded to the donor. Recipients do not have to explicitly consent according to Data protection laws (i.e. GDPR).</p>
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Examples:

Restrictions could be outside EU any special national policy or if a patient indeed has actively declined that his/her data is shared with the Donor Center.

8. Signature on the form:

DKMS does not request a handwritten signature. A typed name of the person filling out the form is sufficient. Whether the form does need to be signed is at the transplant center's own discretion.