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D4.2 User guide for new Serious (Product) Events and Adverse Reactions S(P)EAR – reporting system

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World Marrow Donor Association (WMDA)

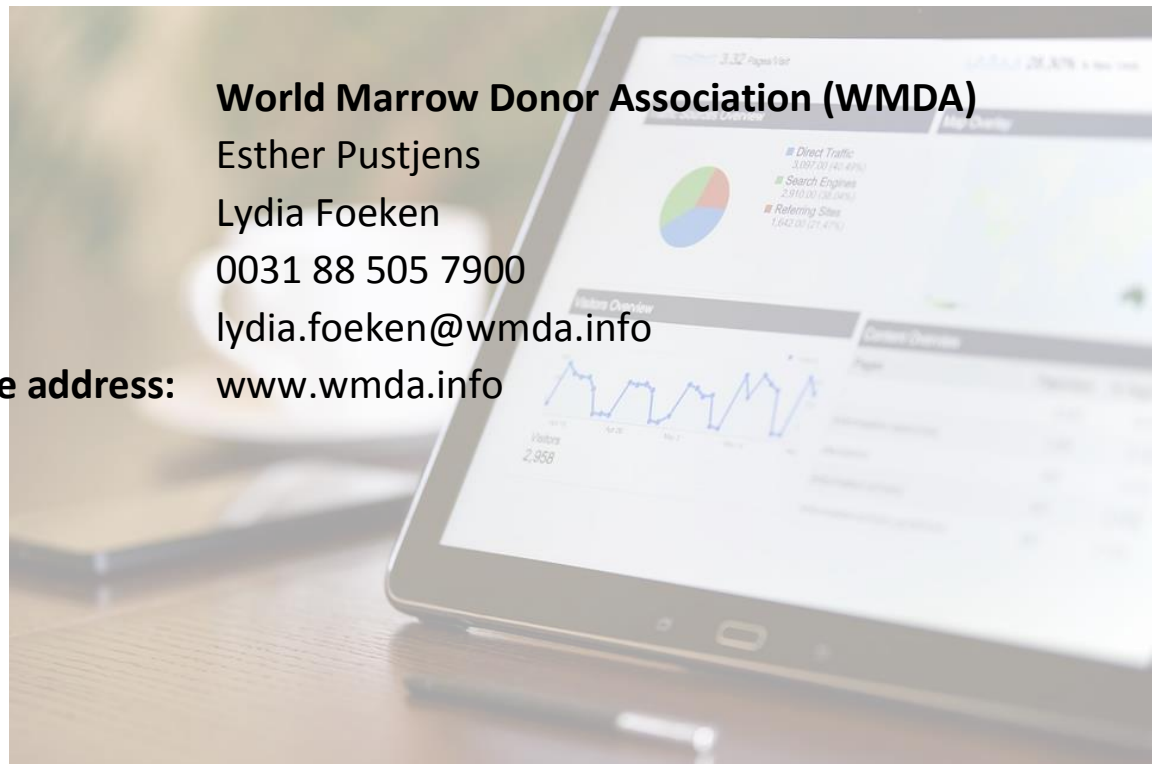
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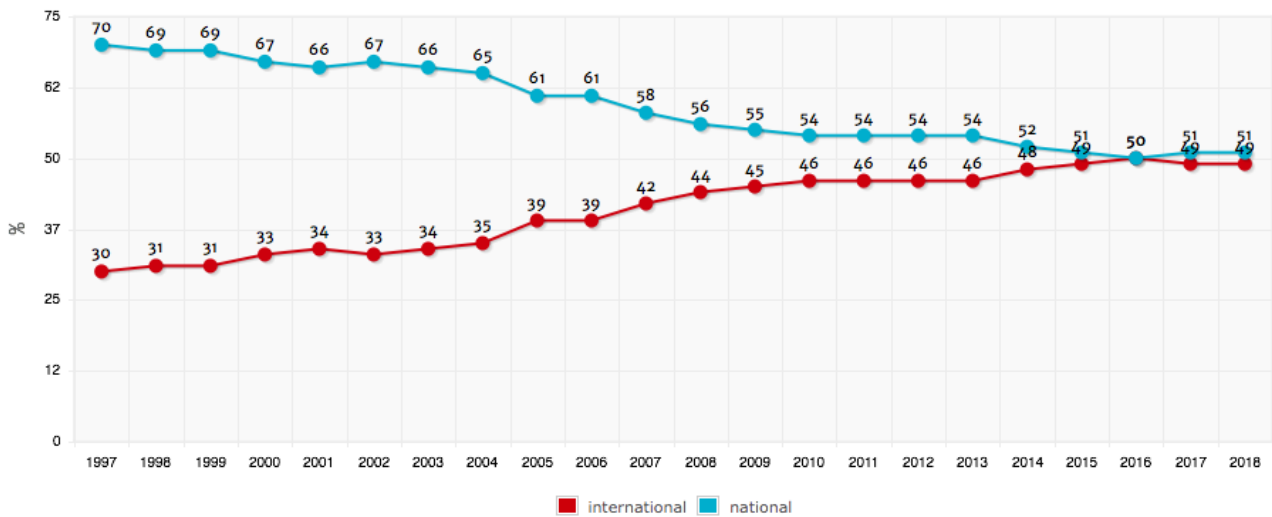
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1. Introduction to S(P)EAR

Every year, more than 21,000 volunteer donors are asked to donate blood stem cells to a patient they do not know. To ensure the continued viability of the global system using volunteer donors, donor health and safety are of critical importance. Because almost half of the blood stem cells collected from volunteer donors for transplantation cross international borders, optimal donor safety requires global strategies (Figure 1).

Figure 1. Percentage of HPC products provided for national and international patients - Date from WMDA Global Trends Report 2018



In July 2019, the World Marrow Donor Association (WMDA) launched a new global online reporting system for WMDA member organisations to report Serious (Product) Events and Adverse Reactions – S(P)EARs – to the WMDA. The EU definitions of a serious adverse event or reaction are as follows:

EU definition of a serious adverse event DIRECTIVE 2004/23/EC, article 3 (m)	EU definition of a serious adverse reaction DIRECTIVE 2004/23/EC, article 3 (n)
‘serious adverse event’ means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity WMDA terminology: Harm to a Donor / Recipient	‘serious adverse reaction’ means 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 WMDA terminology: Risk of Harm

With this system, WMDA collects and analyses information on recipient and donor S(P)EARs which affect donors and/or products from the WMDA stem cell donor registries and cord blood banks.

Furthermore, a rapid alert system is followed for disseminating information on S(PEAR) to all members of the international community in contact with allogeneic donors and patients. On WMDA Share an [Imputability Assessment Tool](#) is available which specifies the adverse reaction severity grades, the adverse reaction imputability and the criteria for serious adverse events.

2. User guide S(P)EAR system

2.1 Rapid alerts

The WMDA office reviews all reported incidents at least once a week. If you have a rapid alert that needs to be shared with the community quickly, we urge you to send a separate e-mail to the WMDA office (sear-spear@wmda.info) or call us on: +31 88 505 7900 as soon as possible.

2.2 Gain access

1. Contact WMDA office by e-mail: sear-spear@wmda.info
Note: WMDA office will then decide whether you are entitled to gain access
2. Go to the online reporting tool <https://wmda.knack.com/spear#>
3. Click on “forgot?” next to Password
4. Enter your email address in the designated field and press the “Submit” button
Note: You will then receive a link to reset your password

2.3 Log-in

1. Go to the online reporting tool <https://wmda.knack.com/spear#>
2. Fill in your email address and password
3. Click on the “Sign In” button
Note: to let the system remember your password automatically tick the box “Remember me”

2.4 Welcome page

1. Choose your role:
 - a. S(P)EAR reporter for organisation (ION-XXXX)
 - b. S(P)EAR reporter for affiliated organisation
 - c. WMDA S(P)EAR Committee
 - d. WMDA office
2. Click on the link “Go to dashboard”

2.5 Overview Dashboard


This shows all reports from your organisation on one overview. The reports are subdivided into:

- a. **In Draft**
Shows all reports that are in draft modus. The reports can be edited or deleted by yourself or a colleague. Reports in Draft modus are not visible for WMDA.
- a. **Submitted to this Organisation**
Shows all reports that are submitted to the reporting member organisation by an affiliated organisation. The reports can be changed by the reporting organisation.
- b. **Additional Information Requested**
Shows all reports that require additional information from WMDA.

- c. **Unlocked to Edit**
Shows all reports that have been unlocked by WMDA to make it possible to edit the report. This could be done on request of the organisation.
- d. **Submitted to WMDA**
Shows all reports that have been submitted to WMDA by the reporting member organisation
- e. **Ready for Committee**
Shows all report that have been continued by WMDA office to the S(P)EAR Committee
Note: Only visible for S(P)EAR Committee members and WMDA office
- f. **Reviewed by Committee**
Shows all reports that have been reviewed by the S(P)EAR Committee

Note: Click on the link “view” in the different sections to view the report. Reports can be categorised into ‘Report ID’, ‘Type of Report’, ‘Status’, ‘ION’, ‘Organisation’, ‘Created by’, ‘Created on’ and ‘Updated On’.

2.6 Generate a S(P)EAR report

1. Click on the button “Add Report” to add a new S(P)EAR report
2. Choose the Type of Report you would like to submit
 - a. **Harm to a donor:** Choose this category to report an adverse reaction in a donor during or after a donation procedure. You can use this category to report other negative consequences for the donor, such as unnecessary procedures. This category is comparable to what was previously called a 'SEAR'.
 - b. **Harm to a recipient:** Choose this category to report an adverse reaction in a recipient during or after the infusion of a cell product. You can use this category to report any harm in a recipient as a consequence of product quality issues, delay in delivery etc. This category is comparable to what was previously called a 'SPEAR'.
 - c. **Risk of harm:** Choose this category to report any problem or incident that could have had (but did not have) negative consequences for the donor or the recipient or the system (as a whole).
3. Click on the button “Continue”
4. Fill in all highlighted tabs *Please see Chapter 6 for more detailed information*
Note: Depending on the Type of Report you choose, different tabs will be highlighted
 - Selecting the preferred tab can be done by clicking on it.
 - Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 can be accessed [HERE](#).
 - International Statistical Classification of Diseases and Related Health Problems 10th Revision can be accessed [HERE](#).
 - Date notification in the calendars is in ISO date format MM/DD/YYYY. It is possible to choose the date in the calendar tool or fill in manually. In case “Date of collection” is not applicable, please fill in 01/01/1999.
 - A drop-down menu requires you to click on the  and choose one of the following options. Selecting one can be done by clicking on the preferred choice or by typing in the first letter.
 - It is possible to enter text with cut and paste into free text fields, the text is automatically truncated if the permitted number of characters is exceeded.

- Questions marked with a * are mandatory. The report cannot be submitted to WMDA without filling on this section. You will see red warning messages at the top of each page and at the “Review & Submit” page if certain fields have not been filled in.
- Certain fields become visible if first specific answers were given.
- It is possible to upload up to 5 documents (e.g. photographs of bags, and/or dry shipper or letter with more information, transport information). The maximum file size is 10 mb. Note: WMDA does not accept privacy-sensitive information in the data provided. Please double check.

Explanation of symbols:

* Mandatory questions

? Additional explanation of the question

5. Saving your data can be done by clicking on the “Save” button or by clicking on the next tab (it will be saved automatically)
6. To finalise the report:
 - a. Click on the tab “Review and Submit”
 - b. Double check all your data. Make sure to fill in all mandatory questions
 - c. Remove any confidential patient/donor related data
 - d. Click on the button “Submit to WMDA”
 - e. Once the report is submitted, it is possible to print the report by clicking on the button “Print” at the top of the report

2.7 (confidential) Comments

After the report is submitted to WMDA, comments can be added. The comment sections are visible at the bottom of a report under the ‘view’ option. Two sections can be distinguished:

1. Comment section is for WMDA office and the S(P)EAR Committee to ask for addition information or clarification. It can be used for communication between member reporting organisation and their affiliated organisations. Click on “Add Comment”
2. Confidential comment section is for communication between WMDA office and the S(P)EAR Committee

2.8 Log-out

Press on the link “Log Out” in the upper right corner to log out of the system. Draft versions will be automatically saved. At a later time, you or a colleague can continue editing the report.

2.9 Annual S(P)EAR reports

All S(P)EAR reports will be reviewed by the WMDA medical consultant. In case additional information is needed, WMDA office will inform you via the comment section under a report. If all necessary information is provided, WMDA office will forward the report to the S(P)EAR Committee which will discuss the provided information during monthly conference calls. More information about the tasks and responsibilities of the S(P)EAR Committee can be found in the [WMDA S\(P\)EAR Committee Operating Document](#).

Annually, WMDA office analyses and summarises all provided S(P)EAR data. This is then published in annual S(P)EAR reports which are published on WMDA Share, available for the WMDA community.

S(P)EAR annual reports

- [WMDA S\(P\)EAR report 2018](#)
 - [WMDA S\(P\)EAR report 2017](#)
 - [WMDA S\(P\)EAR report 2016](#)
 - [WMDA S\(P\)EAR report 2015](#)
 - [WMDA S\(P\)EAR report 2014](#)
 - [WMDA S\(P\)EAR report 2013](#)
 - [WMDA S\(P\)EAR report 2012](#)
 - [WMDA S\(P\)EAR report 2011](#)
 - [WMDA S\(P\)EAR summary report 2003 - 2010](#)
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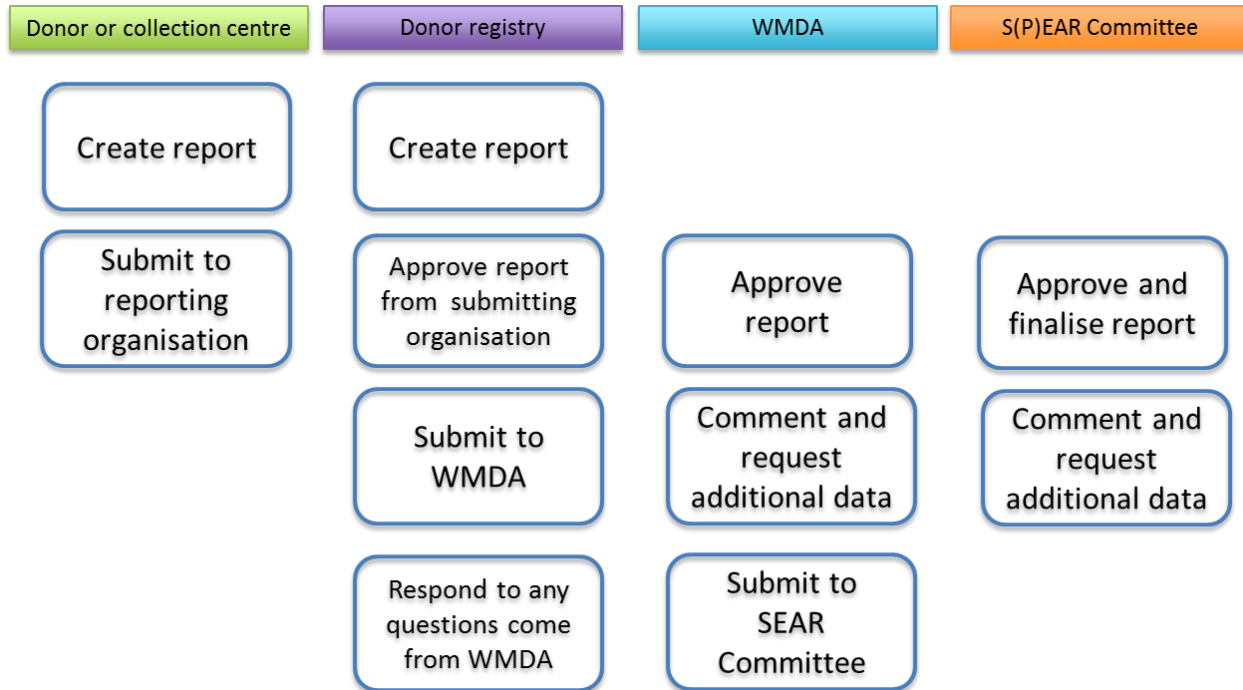
2.10 Contact details

To get access to this new online reporting system (as a S(P)EAR reporter), to send us your feedback or if any questions in the reporting form are unclear, missing or not relevant, please let us know. You can contact the WMDA S(P)EAR project coordinator by e-mail via sear-spear@wmda.info

3. Process flow

The workflow of the S(P)EAR reporting includes donor, transplant or collection centre (= affiliated organisation), donor registry (= WMDA member organisation), S(P)EAR administrator (= WMDA office) and S(P)EAR Committee (= expert members from WMDA member organisations worldwide). This is visualised in *Figure 2*.

Figure 2. Workflow S(P)EAR reporting



- Donor, transplant or collection centre (affiliated organisations)

Donor, transplant or collections centres are affiliated with donor registries in case of unrelated stem cell donation. To reduce manual typing of incidents, these organisations have the possibility to create reports and submit them to the reporting organisation/donor registry. The further handling of the report will go via the donor registry.

- Donor registry

These reporting organisations oversee approving reports from the submitting organisation. In addition, they have the option to create or improve a report and the tasks to submit them to WMDA. Furthermore, they need to response to any questions that WMDA office or the S(P)EAR Committee might have related to the reported incident and submit additional information of requested.

- WMDA office

The WMDA office team for SEAR/SPER reporting consists of a medical advisor and a project coordinator. The tasks of the medical advisor include reviewing all reported incidents at least once a week and checking for rapid alerts. In addition, if necessary, provide reporting organisations with feedback on their case or request for additional information. If the report is approved, it will be turned over to the S(P)EAR Committee.

The project coordinator regulates all issues related to the S(P)EAR reporting and keeping the online reporting system running.

- S(P)EAR Committee

The S(P)EAR Committee consists of 11 medical experts from worldwide WMDA member organisations. Their main task is to review and finalise the reports every month. If necessary, they can request additional information. In case of a Rapid Alert, they will ad-hoc plan schedule a meeting to discuss the issue, followed by sending out the Rapid Alert to the WMDA community if required.

4. FAQ and practical tips

1. How can I become a S(P)EAR reporter?

The first step is to check with the CEO or manager of your organisation. Followed by contacting the WMDA office to get instructions about accessing the system. Please contact the S(P)EAR project coordinator by e-mail: sear-spear@wmda.info

2. How can I log into the system?

Go to <https://wmda.knack.com/spear#welcome/> and log-in with the email address and password. If you do not have a password yet, press 'forgot?' next to password. You will then be guided to the 'Forgot your Password' page. After filling in your email address, you will receive the password to be used to log in.

3. Can I get help with the imputability?

To perform an imputability assessment, WMDA created the [Imputability Assessment Tool](#).

4. What to report and what not to report?

Check the document [S\(P\)EAR examples of what to report and what not to report](#).

In addition, see the [Standard Operating Procedure](#) for reporting SEAR/SPEAR on WMDA Share. More education:

On 4 March 2020, WMDA's medical advisor will give an education webinar on this topic. How to sign up will be promoted via Stem Cell Matters. If you are not able to attend this webinar, there will be an option to review at a time that is more sufficient for you.

5. How often are the reports reviewed?

At least once a week, WMDA's medical advisor check the reports to make sure there is not a Rapid Alert.

6. What does a Rapid Alert mean?

A Rapid Alert can be sent out in the rare case of a donor death, or if the chair of the S(P)EAR Committee deems a S(P)EAR report to require expedited reporting. An ad-hoc meeting of the S(P)EAR Committee will then be called withing 5 working days to review the event.

If you have a rapid alert that needs to be shared with the community quickly, we urge you to send a separate e-mail to the WMDA office (sear-spear@wmda.info) or call us on: +31 88 505 7900.

7. Will I receive feedback on the report and in what time frame?

In general, you will not receive any feedback. WMDA and/or the S(P)EAR Committee could ask for additional information, visible via comments under the report.

8. What happens with me reported incident?

All reported incidents are collected in the system and will be analysed. They will be shared anonymously with the WMDA community in annual S(P)EAR reports.

5. Common issues and pitfalls

WMDA has organised several educational events and webinars to create awareness for the new system and the user-friendly way it operates. Despite this, there is a long journey to go to explain the need of serious adverse events reporting. The registries have implemented the reporting in their workflows and for WMDA qualified organisations it is mandatory to report to WMDA. In 2020, the WMDA would like to explore if the organisations are over or underreporting to WMDA.

Not all WMDA member organisations have signed up to the system. This might be because their activity is too low or they have not had an incident to report. In 2020, the WMDA will reach out to each member organisation to make sure that they have registered their medical director as SEAR/SPEAR reporter.

The root-cause analysis is not always understood by reporters. This is a new area of questions and WMDA members are not used to report in this way. This means that there is additional work to get the information complete and understandable for committee review. In 2020, the WMDA will organise a webinar to educate the reporters about root-cause analysis.

The software application has bugs, which were detected late after launch. As the project was already above the defined budget, it was not possible to solve the bugs quickly. A discussion about warranty period took long. The bugs will be solved in 2020.

The system requires a new workflow for the WMDA office team. In 2020, the workflow will be critically reviewed in order to improve services to member organisations.

6. Detailed description questionnaire S(P)EAR reporting

Type of Report form

- **Type of report ***

Please choose one of the three following options:

Harm to a donor: Choose this category to report an adverse reaction in a donor during or after a donation procedure. You can also use this category to report other negative consequences for the donor, such as unnecessary procedures. This category is comparable to what was previously called a 'SEAR'.

Harm to a recipient: Choose this category to report an adverse reaction in a recipient during or after the infusion of a cell product. You can also use this category to report any harm in a recipient as a consequence of product quality issues, delay in delivery etc. This category is comparable to what was previously called a 'SPEAR'.

Risk of harm: Choose this category to report any problem or incident that could have had (but did not have) negative consequences for the donor or the recipient or the system (as a whole).

- **Long/short-term harm ***

For reporting of harm to a donor, please choose *between Harm to donor less than or equal to six months OR Harm to donor more than six months after donations (potentially due to hematopoietic stem cell donation)*.

Description of Harm form

- **Date reporting registry was informed about the complication**

Please fill in the correct date (ISO date format MM/DD/YYYY). Click on the field to select a date. The date can be changed by clicking on the forward and back arrows.

- **Date donor/recipient complication or adverse reaction is detected**

Please fill in the correct date (ISO date format MM/DD/YYYY). Click on the field to select a date. The date can be changed by clicking on the forward and back arrows.

- **Please describe donor/recipient complication/adverse reaction/consequences (max 9000 chars) ***

Please enter any additional relevant details about the incident. Please provide full detail of dates, times and names of persons involved where necessary.

- **Please specify relevant lab results (max 9000 chars)**

Examples in case of a bone marrow collection: haemoglobin level, day of return to normal levels.

Examples in PBSC collection: highest WBC in peripheral blood, lowest platelet count, lowest calcium levels, first day of normal

results of WBC platelets or any other relevant abnormal results

- **Did the donor/recipient receive any blood products?**

Please select Yes or No.

- **What kind of blood products did the donor/recipient receive? ***

If Yes, please specify: autologous or allogeneic, give further explanation if relevant

- **Number of red blood cells *** If applicable, please fill in the correct number
- **Number of platelet units *** If applicable, please fill in the correct number
- **Number of plasma units *** If applicable, please fill in the correct number
- **ICD-10 code**

Please classify harm / risk of harm to a donor according to ICD-10. While the three-character category (e.g., C50 breast cancer) suffices, any additional subcategories are welcome. Detailed explanation and guidelines are available on the [WHO site](#).

- **Describe the treatment given and measures taken**

Please give a short description of the treatment and measure that were taken.

Product Specification form

- **Type of (intended) cell product ***

Please select one option. Enter the product type the recipient received. If the recipient has had more than one transplant or did not receive intended transplant, enter the product type that is associated with this Adverse Event.

- **Please specify ***

If “Other” is chosen as the product type, specify the product type here.

- **Source ***

Please select one option.

- **If relevant or applicable: number of involved bags.** Please select the correct number
- **If relevant or applicable: number of involved bags.** Please select the correct number
- **Product ID-number**

Please only fill in product-ID if you really need this for your own identification purpose or on request of WMDA (in case double reporting is suspected).

- **If relevant or applicable: additional product ID-numbers** *paragraph text*

If multiple bags were used please provide individual ID on product bag.

Product ID-number 2 If applicable, please provide individual ID on product bag

Product ID-number 4 If applicable, please provide individual ID on product bag

Product ID-number 3 If applicable, please provide individual ID on product bag

Product ID-number 5 If applicable, please provide individual ID on product bag

- **(Intended) date of collection ***

Please fill in the correct date of collection (ISO date format MM/DD/YYYY). Click on the field to select a date. The date can be changed by clicking on the forward and back arrows. If more than one day of collection, then provide additional date and (if relevant) Product info.

- **If applicable: additional date of collection**

Please fill in the correct date of collection (ISO date format MM/DD/YYYY). Click on the field to select a date. The date can be changed by clicking on the forward and back arrows.

- **Was the product cryopreserved?**

Please select Yes or No.

- **Was there any processing or manipulation to the product that may have contributed to this occurrence?**

Please select Yes or No.

- **Please describe the product processing or manipulation that may have contributed to this occurrence?**

Please give a short description.

Donor details form

- **Donor ID or GRID ID**

Please only provide the Donor ID if you really need this for your own identification purpose or on request of WMDA (in case double reporting is suspected).

- **Sex ***

Please enter the donor's sex.

- **Height (in cm)**

Please fill in the height of the donor in cm. If the exact height is not known, please enter an estimate.

Weight (in kg)

Please fill in the weight of the donor in kg. If the exact weight is not known, please enter an estimate

- **Donor complication occurred ***

Select the appropriate stage involved in the donation and transplantation process where the donor complication

- **Was the collection procedure completed?**

Please select Yes or No.

- **Please specify the number of Days/Months the issue arose after the collection procedure.**

Select the number of days in the drop-down menu.

- **Please specify the number of Months/Years the issue arose after the collection procedure. ***

Select the number of months/years in the drop-down menu.

Donation details form

- **Did the selection criteria or the medical examination for this donor differ in any way from your normal selection criteria?**

Please select Yes or No.

- **Please describe in what way the selection criteria/medical examination differed from your normal selection criteria? ***

Please give a short description here.

- **Did the donor have a medical history, medical condition or abnormality prior to donation that might have influenced the occurrence of the event as reported?**

Please select Yes or No.

- **Please describe the donor's relevant medical history, medical condition or abnormality prior to donation**

Please give a short description here.

- **Were mobilising agents given to this donor? ***

Please select Yes or No.

- **Please specify which mobilising agent was given ***

Please select the correct mobilising agent from the drop-down menu.

- **Please specify which "Other" mobilising agent was given ***

If chosen "other", please specify here.

- **Which filgrastim/lenograstim? ***

Please select the correct option from the drop-down menu.

- **Please specify which "Other" filgrastim/lenograstim was given ***

If chosen "other", please specify here.

- **Dose administered (microgram/kg/day)**

Please fill in the correct dose.

- **Number of days administered**

Please fill in the correct number of days.

- **Was a central line (central venous catheter) used?**

Please select Yes or No.

- **Which catheter used?**

Please select from the drop-down menu.

- **Please describe (which other catheter) ***

If applicable, please give a short description

- **Did the mobilisation and collection (including the anaesthesia in the case of bone marrow collection) proceed according to your protocol?**

Please select Yes or No.

- **Please describe in what way the mobilisation and collection did not conform to your protocols? ***

Please give a short description.

- **Were there symptoms or out-of-range results to which staff had to respond?**

Please choose Yes or No.

- **Please describe the symptoms or out-of-range results that the staff had to respond to? ***

Please give a short description.

Recipient Details form

- **Sex of recipient**

If you are reporting a Risk of harm event involving a recipient, please enter the recipient's sex. If you are reporting of Harm event involving a donor or the product, select "Not applicable".

- **Recipient date of birth**

Please fill in the date of birth of the recipient (ISO date format MM/DD/YYYY).

Transplantation Details form

- **Was the transplant performed as planned?**

Please select an option from the drop-down menu.

- **Please give the duration of the delay (in days) ***

Fill in the number of days.

- **Please give the duration of the delay (in days) ***

Fill in the number of days.

- **What was done with the product? ***

Please give a short description.

- **Was the cell dose supplied? ***

Please select an option from the drop-down menu.

- **Please select the type of cell dose requested ***

Please select an option from the drop-down menu.

If you are reporting a Risk of harm event and the dose is not known and not relevant, you may enter Not applicable or Other.

- **Cell dose requested (cells per kilogram recipient) ***

If applicable, fill in the correct number of the specific cell type.

- TNC (10E8) ***
- CD34+ (10E6) ***
- CD3+ (10E8) ***
- MNC (10E8) ***
- Other, please specify *** Fill in another cell type, not listed above.
- Cell dose supplied /kg recipient weight *** Fill in the cell dose here
- **Was the product viability sufficient?**

Please select Yes or No.

- **Please provide the viability %?**

Please provide the correct viability % between 0 - 100 without decimals.

- **Was the product infusion completed?**

Please select Yes or No.

- **Did engraftment occur?**

Please select Yes or No.

Investigation of Problem or Incident

- **Did a problem or incident occur which may have resulted in or contributed to harm to donor/recipient?**

Please select Yes or No.

If a problem or incident occurred which could have caused or contributed to the harm which you are reporting (donor or recipient), select Yes. If there was no relevant problem or incident, select No. If there was a problem or but it was unrelated to the harm which you are reporting, consider submitting a separate report.

- **Date problem or incident detected ***

Enter the onset date for the adverse event (ISO date format MM/DD/YYYY). If the exact date is unknown enter the investigator determined the adverse event to meet the adverse reporting criteria. This question is required for products.

- **Please describe problem or incident ***

Describe when you have selected: risk of harm or if problem/incident may have resulted in harm to donor/recipient. a description of the adverse event. Include such details as pertinent signs and symptoms, laboratory values, radiographic or pathology findings, and any other procedures/actions taken. This question is required for all products.

- **Phase in procedure where problem or incident occurred ***

Please select an option from the drop-down menu.

If there was more than one error or failure, enter the phase where the first error or failure occurred. Use Other if in doubt and explain.

- **Was a human error detected which potentially caused or contributed to the problem or incident? E.g. administrative or communication error, testing or processing error.**

Please select Yes or No.

Was a human error detected in your institution which potentially caused or contributed to the problem or incident? error or failure occurred outside your organisation, WMDA cannot handle this. Encourage the other organisation report.

- **Type of human error ***

Please select from the drop-down menu.

If there was more than one human error or failure, give details of the first human error or failure. If you wish to multiple human error or failures, you could select the not specified option and provide details in the Please specify box.

- **Please specify the type of human error if it is not listed above? ***

Please give a short specification of the type of human error if it is not listed above.

- **Additional information regarding the type of problem or incident and step in procedure (e.g. insufficient inadequate anticoagulant used, processing error because staff member inadequately trained)**

Here you can give more detailed information regarding the type of problem or incident.

- **Corrective or preventive measures following this problem or incident**

Here you can give more detailed information regarding the corrective or preventive measures following the problem or incident.

Investigation of Transport Problems form

- **Type of incident**

Please select from the drop-down menu. Choose the option that best reflects the (root) cause.

- **If "Other", please describe ***

If chosen "other", give a short description here.

- **Was the courier from**

Please select from the drop-down menu.

- **Please specify "Other" courier from ***

If chosen "other" at the previous question, you can specify here. WMDA does not need details of commercial courier.

- **Was the product viability affected?**

Please select from the drop-down menu.

- **Please describe what technique was used to determine the effect on the viability of the product ***

Please give a short description.

Finalisation form

- **Type of harm to donor ***

Please select from the drop-down menu.

- **Please specify the other type of harm to donor which hasn't been listed above ***

Please select from the drop-down menu.

Use these categories only if categories above are not applicable.

Please describe the other type of harm to donor if it is not listed above? *

Here you can provide a short description of the other type of harm to donor if not listed above.

- **Type of harm to recipient ***

Please select from the drop-down menu.

Please only report cytogenetic abnormalities in donor cells if this is associated with harm to a recipient

Please specify the other type of harm to recipient which has not been listed above? *

Here you can provide a short description of the other type of harm to recipient if not listed above.

- **Type of problem or incident - (risk of) harm to donor ***

Please select from the drop-down menu.

- **Please specify the "Other" type of problem or incident - (risk of) harm to donor ***

Here you can provide a short description of the other type of problem or incident – (risk of) harm to donor.

- **Type of problem or incident- (risk of) harm to recipient ***

Please select from the drop-down menu.

Enter "Not applicable" under Other if appropriate

- **Type of product quality issue ***

Please select from the drop-down menu.

Enter "Not applicable" under Other if appropriate

Please describe the "Other" type of problem or incident - (risk of) harm to recipient *

Here you can provide a short description of the other type of problem or incident – (risk of) harm to recipient.

- **Please describe the "Other" type of product quality issue ***

- **Imputability ***

Please select from the drop-down menu. For more information please see WMDA's [Imputability Assessment Tool](#).

- **Severity of reaction ***

Please select from the drop-down menu. Select the most appropriate severity of reaction.

- **Clinical outcome for the donor**

Please select from the drop-down menu.

- **Has this case been reported to your national health authority and/or national health regulatory agency?**

Please select Yes or No.

- **The designated donor - collection or transplant centre is informed ***

Please select Yes or No. Please note that the WMDA will not forward or report back to the applicable donor-, collection or transplant center. It is the reporter's responsibility to make sure that all relevant parties are informed.

- **Upload any documents (e.g. photographs of bags, and/or dry shipper or letter with more information, transport information)**

Here you can upload files. Each file uploaded may not exceed 10mb. The maximum number of attachments may not exceed 5. If you have additional attachments you will be able to supply them during the investigation phase provided that you have completed your contact details.

- **Has the investigation been closed? ***

Please select Yes or No.

- **Organisation internal reference (optional)**

Here you can fill in details for your organisation's internal reference.

- **Are you planning to send an update?**

Please select from the drop-down menu.

- **Have you sent a previous report about this donor or recipient?**

Please select Yes or No.

- **Have you sent a previous report about this donor or recipient?**

Please select Yes or No.

- **Reference number (as known to WMDA) if available**

If applicable, you can fill in a reference number here.

- **Any feedback on the questionnaire?**

Here you can give WMDA feedback on this questionnaire.

- **Consent ***

Please tick the box "By submitting this form you are consenting to the information provided, including your contact details, to be stored securely by WMDA".

Please note that by your completion of this report, you are consenting to the information provided, including your details, to be stored securely by the WMDA. For the purposes of complying with our statutory and legal reporting requirements, details of this report may be shared with other bodies also involved in monitoring activities and in accordance with data protection requirements. This ensures that the information is available to all relevant parties. have the right to request a copy of personal data held by the WMDA and to have any inaccuracies in such data or deleted.