

**USER GUIDE**

# S(P)EAR

**REPORTING SERIOUS (PRODUCT)  
EVENTS AND ADVERSE REACTIONS  
VIA AN ONLINE REPORTING TOOL**

<https://wmda.knack.com/spear>

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## 1. Introduction to S(P)EAR

In July of 2019, the World Marrow Donor Association (WMDA) launched a new global online reporting tool for WMDA member organisations to report Serious (Product) Events and Adverse Reactions – S(P)EARs – to the WMDA. With this global online reporting tool, the 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. Trends and patterns can be identified and if necessary, rapid communication on severe incidents can be disseminated to the global community.

### 1.1 Definition of adverse events

WMDA member organisations and their affiliated organisations are obliged to report to WMDA any unexpected donor and/or patient issue or product quality issue in a timely manner. If necessary, urgent measures can then be implemented to protect donors and/or patients, such as a recall of one or more defective batch(es) from the market or change in policies and procedures.

Any adverse event or reaction, or risk thereof, that occurs during any step in the stem cell donation process can and should be reported in the online reporting tool: S(P)EAR. This includes adverse events or reactions that occur to patients and donors, related and unrelated. The WMDA follows the EU definitions of a serious adverse event or reaction:

EU definition of a serious adverse event	EU definition of a serious adverse reaction
DIRECTIVE 2004/23/EC, article 3 (m) <i>'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.</i>	DIRECTIVE 2004/23/EC, article 3 (n) <i>'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</i>

**WMDA classification: Harm to a Donor / Recipient**

**WMDA classification: Risk of Harm**

### 1.2 The user guide

This user guide to the S(P)EAR online reporting tool is designed to provide background information on the S(P)EAR reporting tool. It outlines how to submit a S(P)EAR report and provides answers to commonly asked questions. If any information is missing or something is unclear to you, please do not hesitate to contact us at: [sear-spear@wmda.info](mailto:sear-spear@wmda.info).

To get access to this online reporting tool (as a S(P)EAR reporter), to send us your feedback or if you have any questions, please let us know. You can contact us via e-mail on: [sear-spear@wmda.info](mailto:sear-spear@wmda.info)

## 2. Quick start

### 1. Log in

In your browser, go to <https://wmda.knack.com/spear> and login with your user name and password.

No account yet? Send an email to [sear-spear@wmda.info](mailto:sear-spear@wmda.info) to request login credentials and to receive further instructions



### 2. Create/submit/view reports

Once you're logged in, click on "Go to dashboard". Here you can write, submit and view your reports. Some reporters will be affiliated to multiple organisations. Please select the dashboard you currently want to use.

The screenshot shows the WMDA S(P)EAR online application. At the top, there's a blue header with the WMDA logo (a globe icon and the text 'wmda'). Below the header, a grey bar says 'Logged in as'. The main content area has a white background. It starts with a welcome message: 'Welcome to the WMDA S(P)EAR online application to report Serious Adverse Events and Reactions.' Below this, there are three lines of text: 'We appreciate that you report S(P)EARs to the WMDA global database.', 'If you have any questions, you can contact us at [sear-spear@wmda.info](mailto:sear-spear@wmda.info).', and 'Please press "Go to dashboard" to write, submit and view your reports.' At the bottom left, it says 'WMDA office (ION-0)'. At the bottom right, there's a red arrow pointing left next to the text 'Go to dashboard'.

### 3. Create a report

In the dashboard you can add a new report or view the reports you've previously submitted. To add a new report click the "Add report" button at the top of the page.

Reports are automatically saved to allow to continue editing at a later time. Previously started reports can be found in the "In draft" table in the dashboard.





Welcome > Dashboard

Logged in as [Account Settings - Log Out](#)

[View Stats Reports](#)

[Add Report](#) ←

In Draft

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	Edit Report	View Report	Delete Draft
No Data										

Submitted to this Organisation

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	View Report
No Data								

Additional Info Requested

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	View Report
No Data								

#### 4. Selecting the type of report

There are three types of report to choose from: Harm to a donor, harm to recipient or risk of harm. Depending on the type of harm you choose, the tool will display different relevant questions.

A brief description of each category can be found on the “Type of report” page (see image below).



Welcome > Dashboard > Add Report

Logged in as [Account Settings - Log Out](#)

Type of Report

**Type of report \***

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).

Select the type of report that best suits the type event you are reporting.

[Continue](#)

## 5. Finalizing the report

Once you've filled out all the necessary information, your report is ready to be submitted. The final tab, titled "Review and submit", will display any issues that need to be solved before the report can be submitted. To submit the report, please click the "submit to WMDA" button that can be found next to the report ID at the top of the page.

1. Click on the tab "Review and Submit".
2. Double check all your data.
3. Make sure to fill in all mandatory questions

The screenshot shows the WMDA reporting system's "Edit Report" page for report ID WMDA-2020-001068. The "Review & Submit" tab is highlighted. A red box highlights a validation message: "The following issues must be resolved before the report can be submitted" followed by "Donor Details: Sex is a required field. Please provide the age of donor at time of (intended) donation." A red callout box points to this message with the text "Fill out any mandatory fields before you continue".

Report ID: WMDA-2020-001068

Details

Report ID	WMDA-2020-001068
Author	-
Org	-
Current Status	In Draft
Created On	2020/07/09 16:06PM

Type of Report

Type of Report \* Harm to a donor

Long/short-term harm \* Harm to donor less than or equal to six months

4. Remove any confidential patient/donor related data
5. Click on the button "Submit to WMDA"

 **WMDA**

Welcome > Dashboard > Edit Report      Logged in as [redacted]      Account Settings - Log Out

WMDA-2020-001068

Navigate between form sections using the tabs. Remember to save your progress with each section.

Type of Report   Description of Harm   Product Specification   Donor Details   Donation Details   Recipient Details   Transplantation Details  
Investigation of Problem or Incident   Investigation of Transport Problems   Finalisation   Review & Submit

**Details**

Report ID	WMDA-2020-001068
Author	
Org	
Current Status	In Draft
Created On	2020/07/09 16:06PM

**Type of Report**

Type of Report \* Harm to a donor  
Long/short-term harm \* Harm to donor less than or equal to six months

To view the reports you've submitted, you can find them on your dashboard. Here you can also view other reports with different statuses (e.g. draft reports, additional information requested and the reports that have been reviewed by the S(P)EAR committee.



## 6. Additional info requested

Once you submit a report, it will be reviewed by the medical advisor. If there are any additional questions or a request for more information, the report will be sent back to you. You can find the report in the “additional info requested” box on your dashboard.

To answer a request for additional information:

1. Go to your dashboard.
2. Open the report by clicking on ‘View Report Details’.

The screenshot shows the WMDA dashboard. At the top, there is a teal header with the WMDA logo. Below the header, the page title is "Welcome > Dashboard". On the right side of the header, it says "Logged in as" followed by a user name and "Account Settings - Log Out". In the center, there is a section titled "In Draft" containing a table with one row of data. The table has columns for Report ID, Type of Report, Status, ION, Organisation, Created By, Created On, Updated On, Edit Report, View Report, and Delete Draft. The data row is: WMDA-2020-001068, Harm to a donor, In Draft, ., ., ., 2020/07/09 16:06PM, 2020/07/15 05:00PM, Edit Report, view, and a delete link. Below this section is another titled "Submitted to this Organisation" with a table showing "No Data". A red arrow points from the "View Report" link in the "In Draft" table to the "View Report" link in the "Submitted to this Organisation" table. Another red arrow points down from the "View Report" link in the "Submitted to this Organisation" table to the "View Report" link in the "Additional Info Requested" table below.

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	Edit Report	View Report	Delete Draft
WMDA-2020-001068	Harm to a donor	In Draft	.	.	.	2020/07/09 16:06PM	2020/07/15 05:00PM	Edit Report	view	<a href="#">delete</a>

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	View Report
No Data								

Report ID	Type of Report	Status	ION	Organisation	Created By	Created On	Updated On	View Report
WMDA-2018-000878	Harm to a donor	Additional Info Requested	.	.	.	2018/01/01 12:09PM	2020/07/14 03:35PM	View Report Details

3. Scroll down to read the question in the Comments section.
4. Provide you answer or additional information via the “Add comment” button.

The screenshot shows the comments section. At the top, there is a search bar with "Comments" and a "search" button. Below the search bar is a table with one row of data. The table has columns for Comment, Posted By, and Posted At. The data row is: Could you provide more information on the on the donor details?, ., and 07/15/2020 5:11pm. A red arrow points from the "Comment" field to the "Add Comment" button. Another red arrow points from the "Add Comment" button to the "Add Comment" button. Below this section is another titled "Confidential Comments" with a table showing "No Data". A "Back to Top" link is at the bottom.

Comment	Posted By	Posted At
Could you provide more information on the on the donor details?	.	07/15/2020 5:11pm

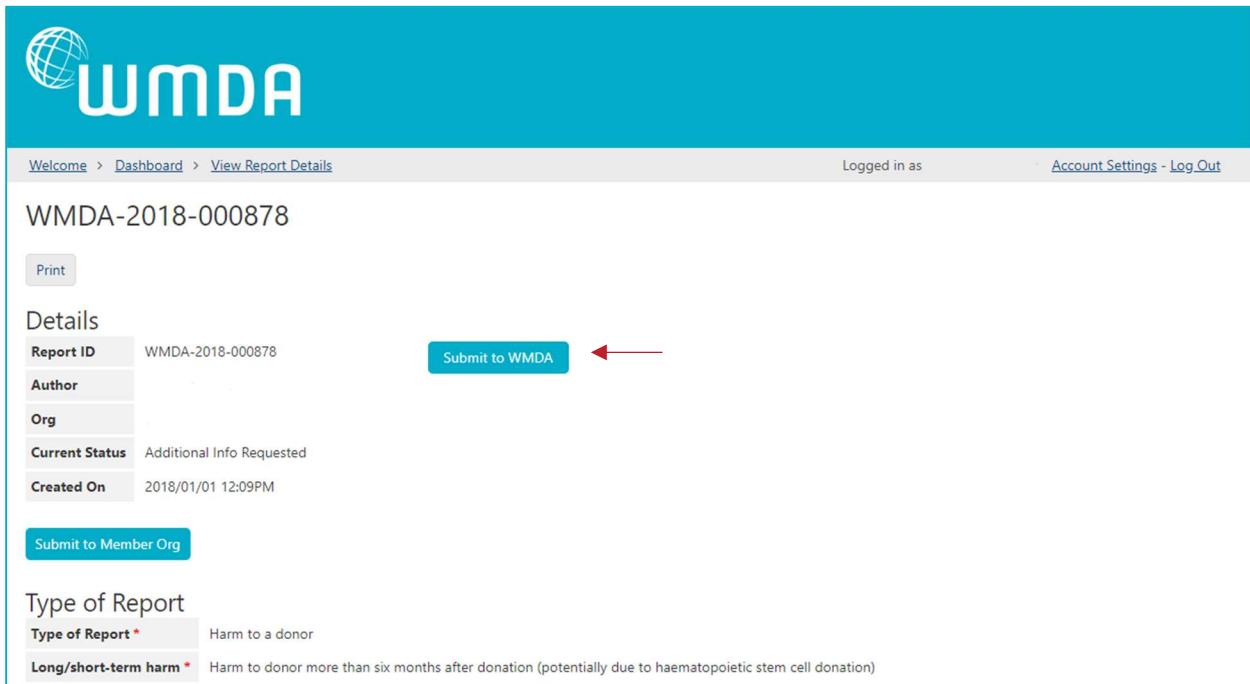
  

Comment	Posted By	Posted At
No Data		

[Back to Top](#)

4. Once you've filled out all the requested information, scroll to the top of the page .
5. Click "Submit to WMDA" to re-submit your report including the additional information.



The screenshot shows a web-based reporting system for WMDA. At the top, there's a logo with a globe icon and the acronym 'WMDA'. Below the logo, the navigation bar includes 'Welcome > Dashboard > View Report Details'. On the right side of the header, it says 'Logged in as' followed by a placeholder account name, with 'Account Settings - Log Out' next to it. The main content area displays a report ID 'WMDA-2018-000878'. There are several data fields: 'Report ID' (WMDA-2018-000878), 'Author' (placeholder), 'Org' (placeholder), 'Current Status' (Additional Info Requested), and 'Created On' (2018/01/01 12:09PM). A prominent blue button labeled 'Submit to WMDA' is located to the right of the status field, with a red arrow pointing towards it from the left. Below these fields is a 'Print' button. Further down, under 'Type of Report', there are two options: 'Type of Report \*' (Harm to a donor) and 'Long/short-term harm \*' (Harm to donor more than six months after donation (potentially due to haematopoietic stem cell donation)).

Please make sure you click the **submit to WMDA** button when you're finished writing your comment to the additional information that was requested. If not, the report will not be sent back to the medical advisor and your input is not submitted.

!

### Reporting a rapid alert

In case of recall or big risks for future donations or transfusions a report can be submitted as a rapid alert. This includes, but is not limited to:

- any prohibition or restriction imposed by the competent authority/health authorities of any country in which the stem cell product is provided or transplanted;
- donor death;

Please **flag** your report as a rapid alert after submitting it by contacting WMDA the by telephone (+31-(0)88 5057900) or e-mail (sear-spear@wmda.info). If the report qualifies as a rapid alert and for dissemination to the international community, it will always be shared without any traceable information on the reporting agency, donor, patient or reporter.

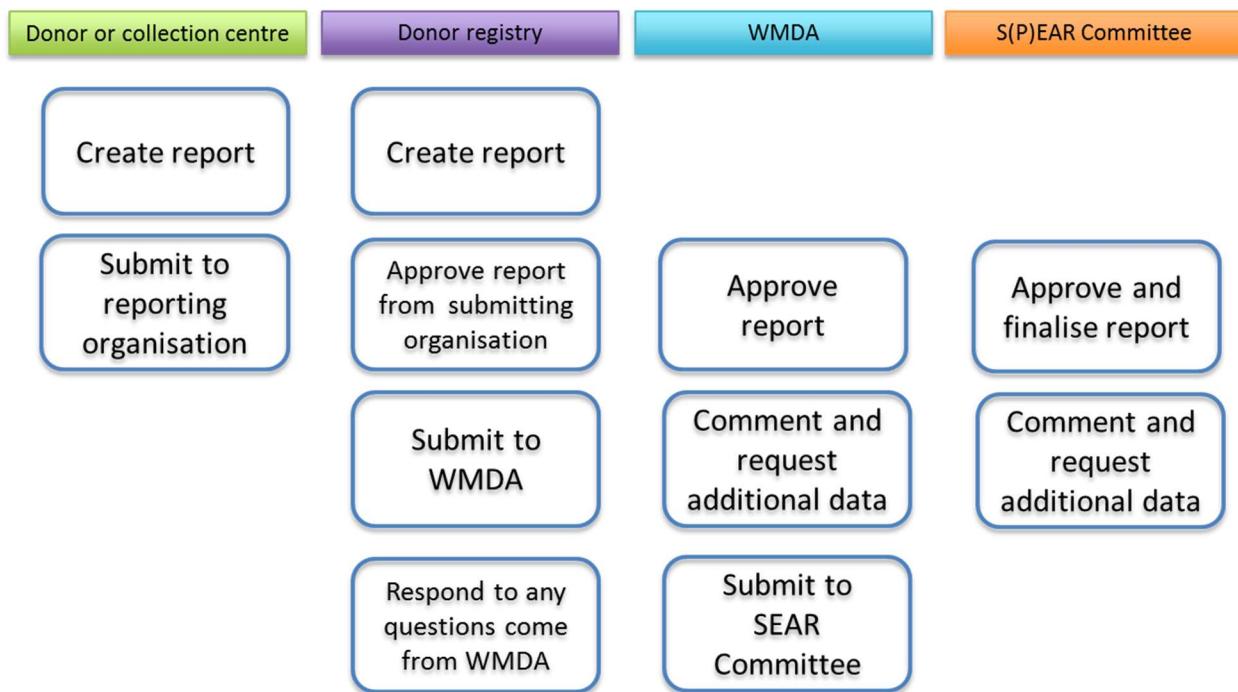
In addition, reporters should notify their competent authorities/health where incident has occurred.

## 4. Process flow

Donor, transplant or collection centres are affiliated with donor registries 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. The donor registry can approve and submit reports from submitting organisations as well as their own incident reports.

When submitted, all reports are available to the WMDA office and the S(P)EAR Committee. The WMDA office team for S(P)EAR reporting consists of a medical advisor and a project coordinator. The medical advisor reviews all reported incidents at least once a week and checks for rapid alerts. If necessary, the medical advisor can request the reporting organization for additional information. If the report is approved by the medical advisor, it will be turned over to the 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 schedule a meeting to discuss the issue, followed by sending out the Rapid Alert to the WMDA community if required.



## 5. Frequently asked questions

### 5.1 How can I become a S(P)EAR reporter?

To become a S(P)EAR reporter, you can contact the WMDA office to receive login details and further instructions on how to access the system. Please contact the S(P)EAR project coordinator by e-mail: [sear-spear@wmda.info](mailto:sear-spear@wmda.info)

### 5.2 How do I login?

Login on <https://wmda.knack.com/spear#welcome/> with your email address and password. If you do not have a password yet, please see question 5.1.

### 5.3 I forgot my user name/password

When you go to the [login page](#) you will find the login module where you can enter your email address and password. Click on “forgot?” next to Password. Enter your email address in the designated field and press the “Submit” button. You will then receive a link to reset your password.

### 5.4 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.

### 5.5 How do I assess the imputability?

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

### 5.6 How do I assess the severity of the reaction?

More information on assessing the severity of a reaction can be found on the page of the Imputability assessment tool (see above).

### 5.7 What ICD-10 reference can I use?

The WHO [online ICD-10 reference tool](#) is used for assigning ICD-10 codes to S(P)EAR reports.

### 5.8 I made a mistake in a submitted report, can I change this?

Once you have submitted a report to the WMDA, you can no longer make changes yourself. If it is an important change or update that needs to be made before the report is reviewed by the medical advisor and or committee, please contact [sear-spear@wmda.info](mailto:sear-spear@wmda.info) and outline the report ID and details of the change request to the WMDA office.

### 5.9 How can I withdraw a submitted report?

Once a report has been submitted, you can not withdraw the report. If withdrawal is necessary, please contact the WDMA office at [sear-spear@wmda.info](mailto:sear-spear@wmda.info) with the Report ID number and the details outlining why the report should be withdrawn. The WMDA office and the medical advisor will then assess if your request for withdrawal will be honored or not.

#### **5.10 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. Once a report has been reviewed by the committee, you can see the committee's final assessment in the Dashboard.

#### **5.11 What happens with the 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.

#### **5.12 What is the annual report?**

Annually, the 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.

#### **5.13 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 within 5 working days to review the event. Rapid alerts consist of a brief description of the event that has occurred (without any information that can trace back to the reporting registry, reporter, patient or donor) and recommendations based on the event that has occurred. The recommendations can be used as a guideline for best practice.

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](mailto:sear-spear@wmda.info)) or call us on: +31 88 505 7900.

## 6. Terminology

TERM	DEFINITION
<b>IMPUTABILITY</b>	An assessment of the likelihood that an adverse event / reaction in a donor or recipient is related to the process of donation or to a safety or quality defect in the transplanted tissue or cells.  Defined as: Definite, Probable, Possible, Unlikely, Excluded, or Not Assessable.
<b>IMPUTABILITY ASSESSMENT TOOL</b>	A online tool developed by the WMDA to help identify the likelihood an event is attributed to the donation or transplantation process.
<b>MEDICAL CONSULTANT</b>	The medical consultant is part of the WMDA committee and works is a medical doctor that works in the field of hematopoietic stem cell transplantation.
<b>REPORT ID</b>	The report ID is a uniquely identifying code that is specific to each report. It is automatically generated when a new report is created.
<b>REPORTER</b>	The reporter is the author of the report and the person that submits the report to the WMDA on behalf of the reporting registry or donor, transplant or collection centre