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USER GUIDE

SPEAR

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

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1. Introduction to SPEAR

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 SPEAR online reporting tool. 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 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* classification*: Risk of Harm*	*'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 classification:* Harm to a Donor / Recipient

1.2 The user guide

This user guide to the PEAR online reporting tool is designed to provide background information on the SPEAR reporting tool. It outlines how to submit a SPEAR 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.

To get access to this online reporting tool (as a SPEAR 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

2. Quick start

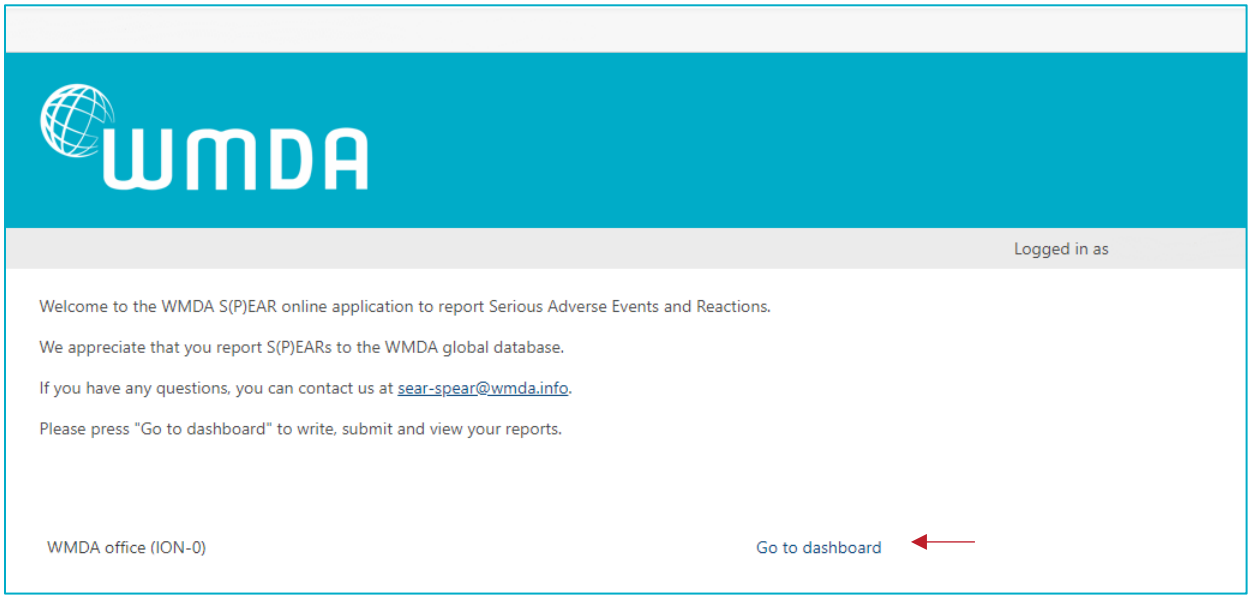
1. Log in

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 to request login credentials and to receive further instructions

2. Create/submit/view reports

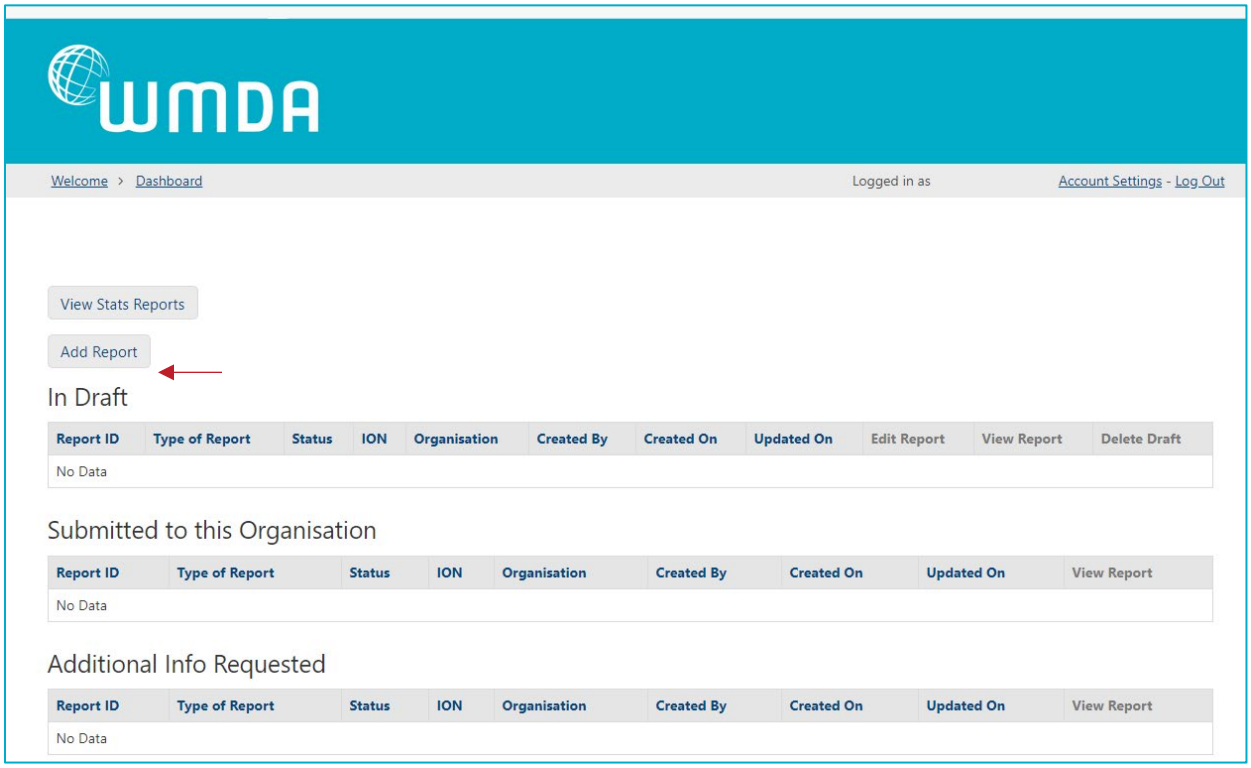
Once you're logged in, click on "Go to dashboard". Here you can write, submit and view your reports. Some reporters will be affiliated to multiple organisations. Please select the dashboard you currently want to use.



3. Create a report

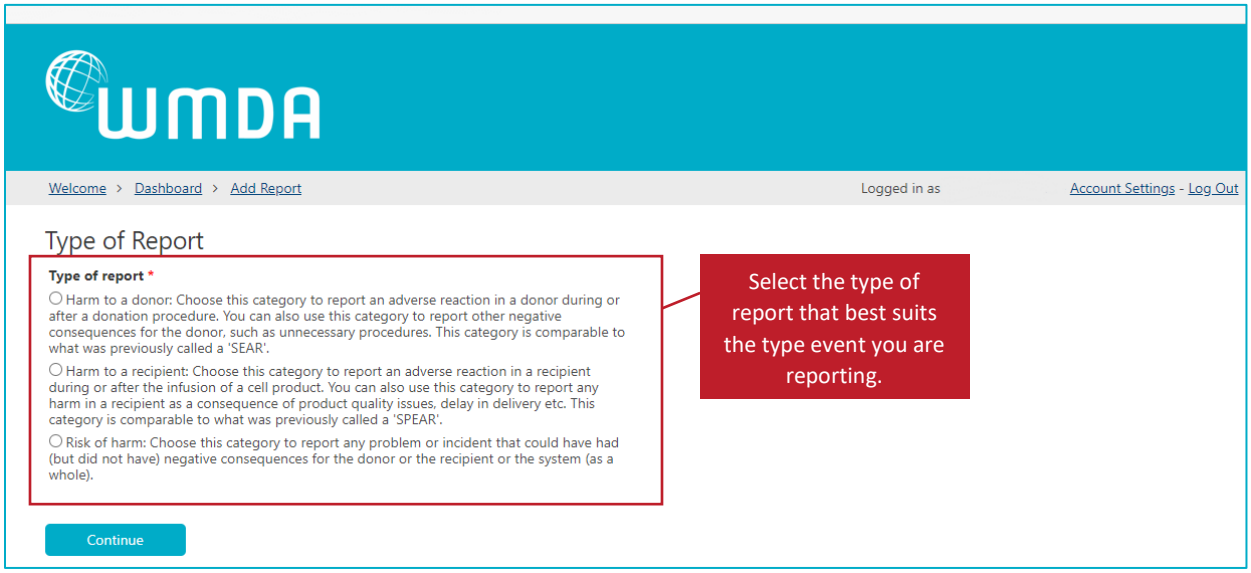
In the dashboard you can add a new report or view the reports you've previously submitted. To add a new report click the "Add report" button at the top of the page.

> 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.



4. Selecting the type of report

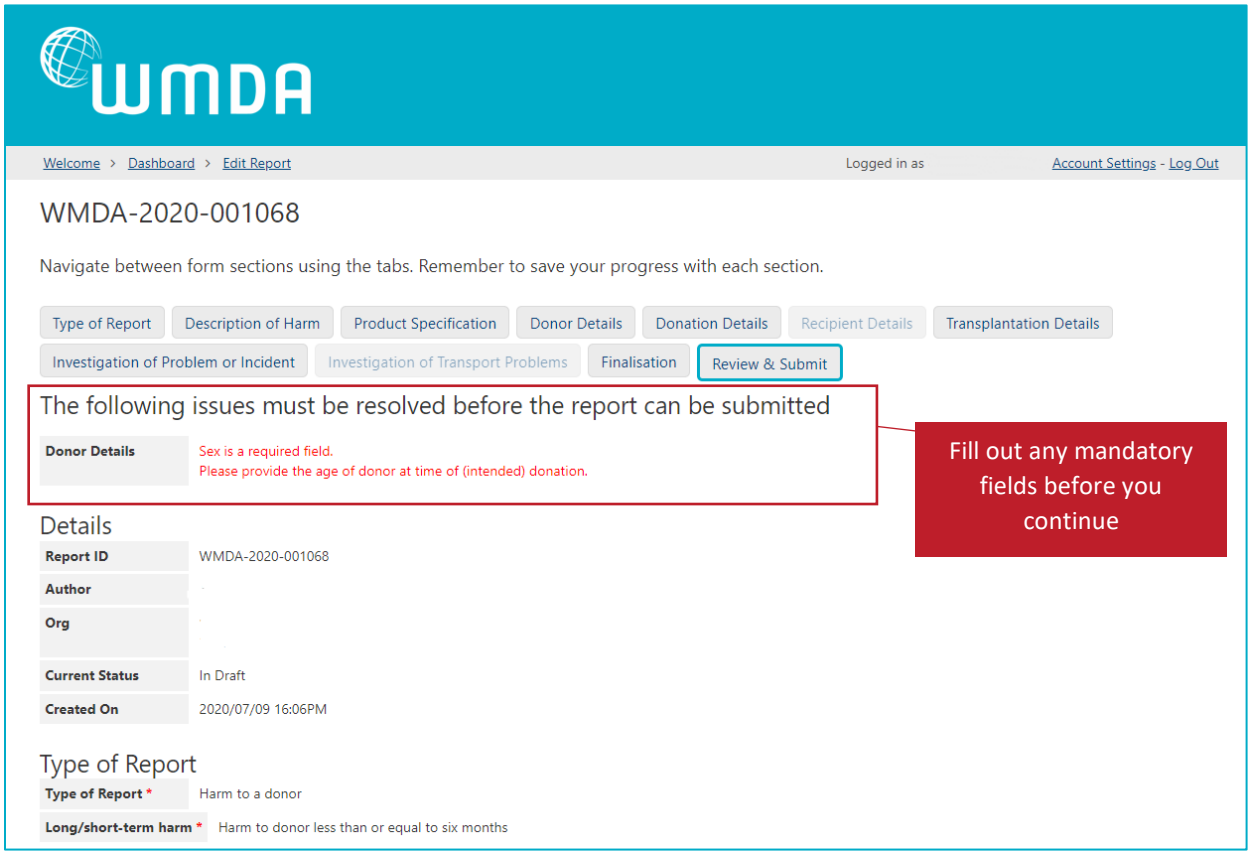
There are three types of report to choose from: Harm to a donor, harm to recipient or risk of harm. Depending on the type of harm you choose, the tool will display different relevant questions. A brief decsription of each category can be found on the “Type of report” page (see image below).



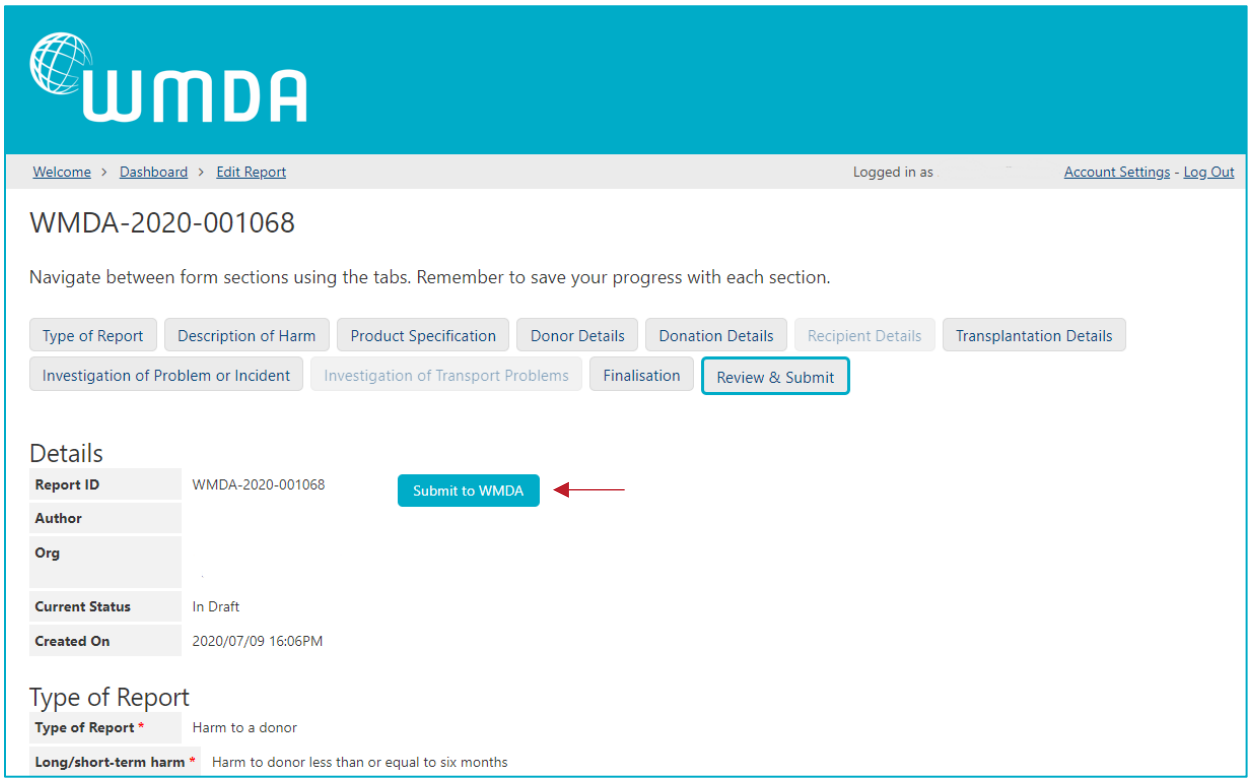
5. Finalizing the report

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



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



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 SPEAR committee.

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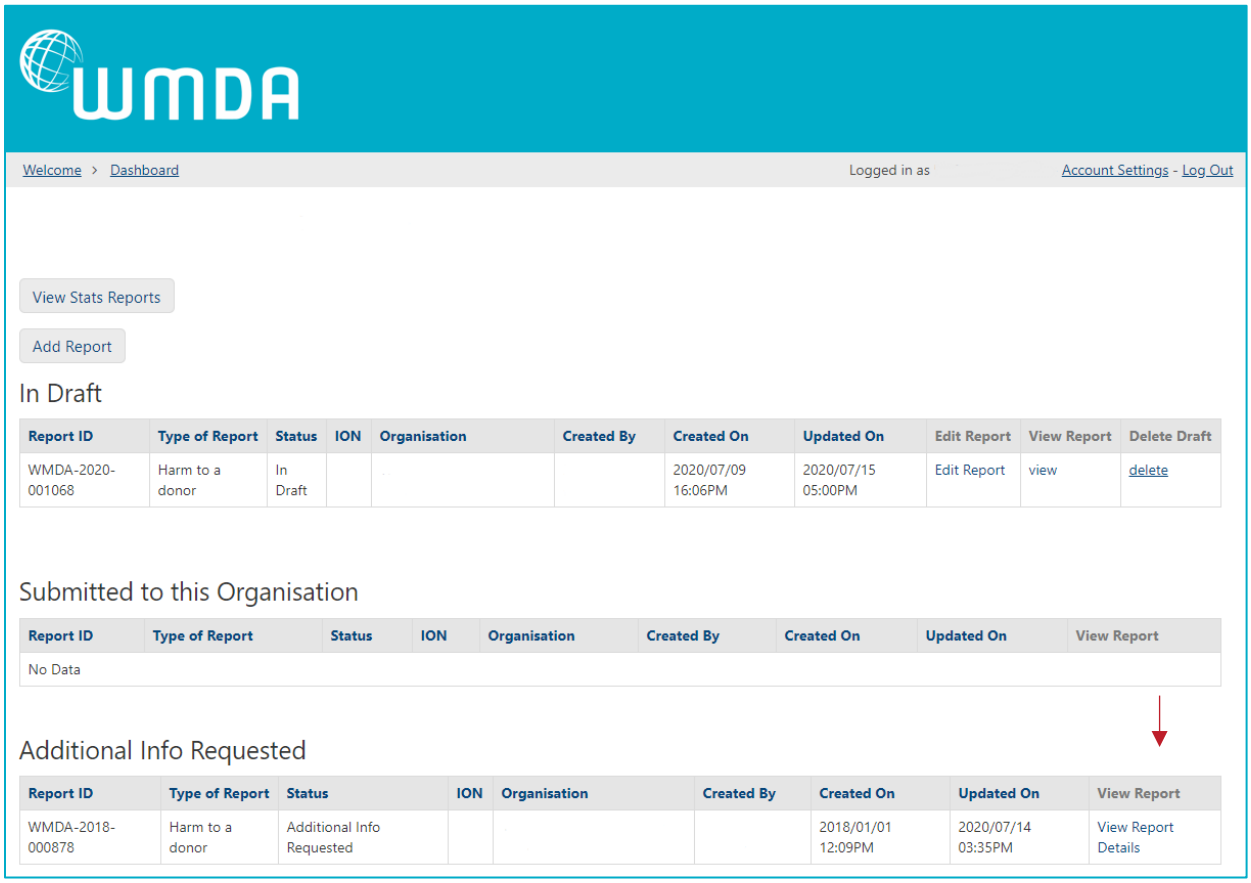
6. Additional info requested

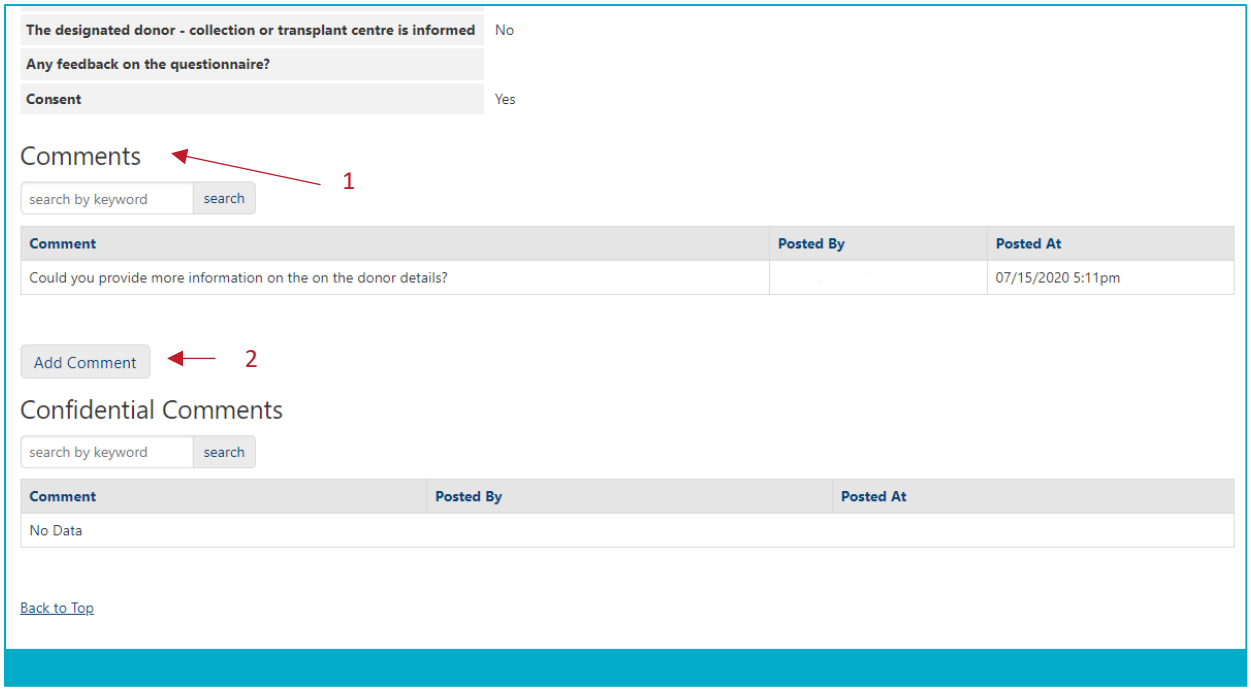
Once you submit a report, it will be reviewed by the medical advisor. If there are any additional questions or a request for more information, the report will be sent back to you. You can find the report in the "additional info requested" box on your dashboard.

To answer a request for additional information:

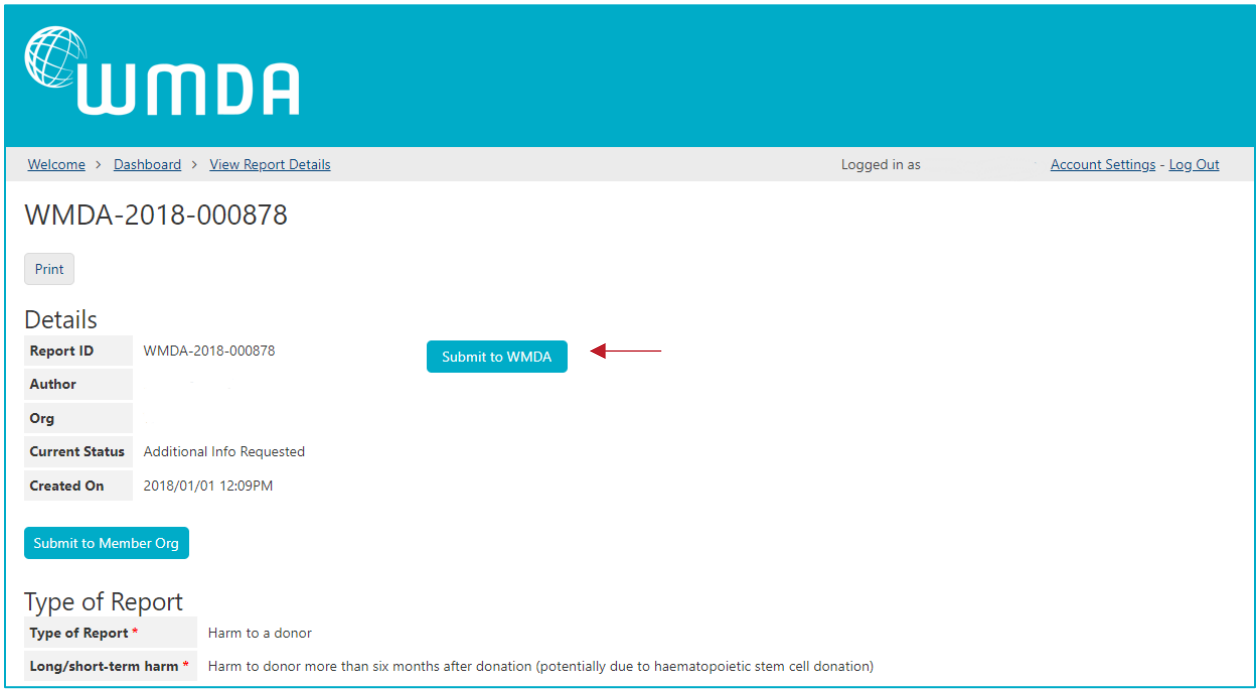
1. Go to your dashboard.
2. Open the report by clicking on 'View Report Details'.



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



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.



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.

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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 SPEAR Committee. The WMDA office team for SPEAR 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 SPEAR Committee.

4.1 The SPEAR committee

The SPEAR Committee consists of various medical experts from worldwide WMDA member organisations. The membership of the group consists of elected representatives of the WMDA membership, the majority with clinical experience, including members of the Clinical, Ethics and Cord Blood Working Groups. In addition to these voting members, the committee also includes one non-voting Regulatory and Legal Affairs member, and one non-voting member from the WMDA Office. A long-term of 6 years may be served, and was felt to be desirable in order for committee members to build up expertise and experience, especially where there is a need to recognise very rare events.

Their main task is to review and assess the data of the SPEAR reports. Each SPEAR report is assigned to a specific voting member who reviews it before the meeting and leads the discussion of the event or reaction. If necessary, a committee member can request additional information or propose a change to the report details. If so, the reporter will be contacted. The committee meets regularly, but 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 SPEAR reporter?

To become a SPEAR reporter, you contact the WMDA office to receive login details and further instructions on how to access the system. Please contact the SPEAR project coordinator by e-mail: sear-spear@wmda.info In this email, please state your full name, organization and if your organization is required to report via an affiliated parent organisation (eg. a national donor registry)

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 the Password field. Enter your email address in the designated box and press the "Submit" button. You will then receive a link to reset your password. Please check your SPAM folder.

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 refence can I use?

The WHO online ICD-10 reference tool is used for assigning ICD-10 codes to SPEAR 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 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 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 SPEAR 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 SPEAR reports.

5.12 What is the annual report?

Annually, the WMDA office analyses and summarises all provided SPEAR data. This is then published in annual SPEAR 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 SPEAR Committee deems a SPEAR report to require expedited reporting. An ad-hoc meeting of the SPEAR 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) or call us on: +31 88 505 7900.

6. Terminology

TERM	DEFINITION
IMPUTABILITY	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.
IMPUTABILITY ASSESMENT TOOL	A online tool developed by the WMDA to help identify the likelihood an event is attributed to the donation or transplantation process.
MEDICAL CONSULTANT	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.
REPORT ID	The report ID is a uniquely identifying code that is specific to each report. It is automatically generated when a new report is created.
REPORTER	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