S(P)EAR CHEAT SHEET

FOR S(P)EAR COMMITTEE MEMBERS

The S(P)EAR committee is responsible for the analysis of the serious (product) events and adverse reactions (S(P)EAR) reports submitted to the WMDA and evaluation of the events/reactions imputability and impact. At the monthly meeting notable reports are discussed. Findings are periodically made available to the public, if expedited is required the committee will share their insights in a rapid alert notification.

TYPE OF S(P)EARS

Harm to donor

An **adverse reaction in a donor** during or after a donation procedure, including unnecessary procedures.

Harm to recipient

An **adverse reaction in a recipient** during or after the infusion of a cell product, including any harm in a recipient as a consequence of product quality issues, delay in delivery etc.

Risk of harm

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).

QUESTIONS?

Find additional documentation on WMDA Share or contact sear-spear@wmda.info

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IMPUTABILITY

Please note: imputability assessment is **only required if** report is a Harm to Recipient report or a Harm to Donor report where harm occurred <6 months after donation.

The **WMDA Imputability Assessment tool** is available on WMDA Share: https://share.wmda.info/x/CgBcCw

SEVERITY GRADE

The WMDA follows the **Common Terminology Criteria for Adverse Events (CTCAE)** guide for severity assessment. Severity grading is only mandatory for Harm to Recipient reports and Harm to Donor reports where harm occurred <6 months after donation.

ACCEPT OR REJECT A REPORT

During assessment, the committee rejects or accepts a report S(P)EAR report. By accepting a report, it can be included in any future data analysis (eg. annual report).

S(P)EAR reports are **only rejected if the report is not valid**. For example: duplicate reports or accidentally submitted reports. Rejected reports will be omitted from any further analysis.

TYPE OF REPORT (ASSESSMENT)

When completing the assessment of a report, choose one or more of the following categorisations. Select the category(-ies) that fit the impact of the report best.

Type of report and follow up:

- **Collect and forward to other WMDA committee/working group**
- **COVID-related report:** to track all reports that are (possibly) COVID-related
- **Educational report:** to create educational material eg. a written piece in our newsletter
- **Not a SEAR:** report is accepted but not event is considered to classify as a SEAR
- **Rapid alert:** requires expedited reporting to notify community
- **Reason for a survey:** request (other) reporters for similar reports
- **Regular report**
- **Possible change of WMDA standards or recommendation**
- **Possible trend**

SPEAR

CHEAT SHEET FOR SPEAR COMMITTEE MEMBERS

ASSESSMENT PROCESS OF S(P)EAR REPORTS BY THE COMMITTEE

Before every monthly meeting, the WMDA office shares an overview with the entire S(P)EAR committee of reports that have the ***Ready for Committee*** status. Each report is assigned to a committee member for reviewal. It is the task of this committee member to assess the S(P)EAR reports assigned to them on completeness and to then provide a classification of each report. This classification, which is used for finalizing the report, reflects the committee's assessment of report type, impact and determines the if any follow up is required. The steps below detail an example work flow.

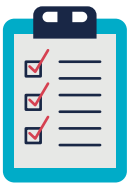
1. Read the details of the report assigned to you

1.1 **Do you have all the necessary information to assess the report (type of event/severity/imputability)?***

- **Yes**: fill out your assessment in the designated columns.
- **No**: write down your questions in the *comments* column and discuss during the monthly meeting if additional information should be requested from the author of the report.

1.2 **Do you have any changes you'd like to propose to the report?***

- **Yes**: fill out the proposed changes in the designated column of the spreadsheet and discuss during the monthly meeting if changes should be requested from the author of the report.
- **No**: continue with filling out your final classification of the report.



**Please note that the report at this stage has already been reviewed by the medial advisor and additional questions may already have been asked to the reporter. Log in to the reporting tool to find out.*

2. Classify the report for finalisation

Once you've established that you have sufficient information to finalize the assessment of a report, the following columns must be filled out:

2.1 **Do you propose to accept or reject this report as a legitimate and complete S(P)EAR report?**

- **Accept if**: the report provides a complete description of a SAE/SAR. Accepted reports are included in analysis
- **Reject if**: reports are only rejected if it's a faulty or 'fake' report, for example: reports that were accidentally submitted. Rejected reports will be omitted from analysis.

2.2 **Please assign a 'type of report' classification to determine if any type of follow up is required.**
See page 1 (**Type of report (assessment)**) for more information on possible classifications.

3. Join the monthly S(P)EAR committee meeting to discuss notable reports

During the monthly meeting you **discuss notable reports** and questions you might have, as well as provide input current discussion topics. Therefore, your attendance is very valuable. After the reports are discussed and the assessment criteria have been provided, the data is entered in the reporting tool by the WMDA office to finalise the report. **The reviewal process is then completed and no more changes can be made.**

Do you have a report or topic that you'd like to put on the agenda to discuss with the committee? Send an email to **sear-spear@wmda.info**

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