

Adverse Events (SPEAR)

Serious Product Events and Adverse Reactions - SPEAR

WMDA has set up a [central global reporting system](#) to report Serious (Product) Events and Adverse Reactions – S(P)EARs – to the WMDA. To access the reporting system, you login with your email address and password. If you do not have a password, contact the [WMDA office](#).

Aim

- To gain insight in the occurrence of serious events and adverse effects in relation to blood stem cell donation by unrelated donors and blood stem cell collection/processing from unrelated donors.

Purpose

- To collect and analyse information on recipient and donor serious adverse events (SAE) and reactions which affect donors and/or products from all WMDA stem cell donor registries and cord blood banks.
- To follow a rapid alert system for disseminating information on SAE/R to all members of the international community in contact with allogeneic donors and patients.



Important note on Rapid Alerts

The SPEAR Committee reviews all reported incidents once a week. If you have a rapid alert that needs to be shared with the community quickly, we urge you to submit it via the [online reporting tool](#) and to immediately send an e-mail to sear-spear@wmda.info or call us on: +31 88 505 7900.

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:

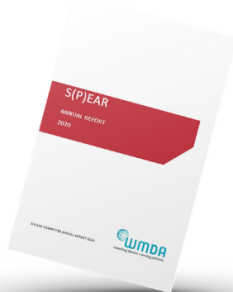
- any prohibition or restriction imposed by the competent authority/health authorities of any country in which the stem cell product is provided or transplanted;
- donor death;

Quick links

- [User guide for SPEAR reporters](#)
- [Access to the SPEAR reporting tool](#)
- [Examples of SEAR/SPEAR reports](#)
- [Common Terminology Criteria for Adverse Events \(CTCAE\) v5.0](#)
- [International Statistical Classification of Diseases and Related Health Problems 10th Revision](#)
- [Notify Library](#)
- [Imputability Assessment Tool](#)
- [Operating of the SPEAR Committee](#)
- [Standard Operating Procedure for reporting SEAR/SPEAR](#)
- [Cheat sheet for SPEAR committee members \(v4\)](#)

Link to annual reports overview (for WMDA members only)

SPEAR Annual Reports



SPEAR rapid alerts

Find below the link to the public WMDA webpage, where you will find all rapid alerts sent out.

[Rapid Alerts](#)