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 thestem 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