Guidelines for the Blood Transfusion Services

22.4: Adverse events and reactions

http://transfusionguidelines.org/red-book/chapter-22-haemopoietic-progenitor-cells/22-4

22.4: Adverse events and reactions

22.4.1: HTA Guide for the management of serious adverse events (SAEs) and reactions (SARs)

All licensed establishments must have a system in place for reporting, investigating, registering and recording information about SAEs and SARs which may influence the quality and safety of tissues and cells, and which may be associated with any licensable activity, as well as any SAR observed during or after clinical application which may be linked to the quality and safety of tissues and cells.

www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance

22.4.2: WMDA reporting system

WMDA maintains a voluntary central global reporting system to report Serious (Product) Events and Adverse Reactions – S(P)EARs as below

https://spear.wmda.info/