International Expedited Reporting

WHITEHALL TRAINING

What is a SUSAR?

Any suspected adverse reaction related to an Investigational Medicinal Product/IMP (the tested IMP and comparators) that occurs in the concerned trial, and that is both unexpected and serious. All SUSARs are subject to expedited reporting.

Additionally, for IMPs without a marketing authorization in any member state of the European Community, any other SUSARs associated with the IMP are subject to expedited reporting.

In general, expedited reporting of SUSARs is required as soon as possible, but in no case later than 15 calendar days of initial receipt of the information by the Marketing Authorization Holder. Timeframes for other types of serious reports vary among countries, depending on source, expectedness and outcome. (ICH E2D)

All ADRs that are both serious and unexpected are subject to expedited reporting. This applies to reports from spontaneous sources and from any type of clinical or epidemiological investigation, independent of design or purpose. (ICH E2A)

Expedited Reporting typically applies only to Individual Case Safety Reports (ICSRs).

In addition, expedited reporting may be required in the following situations:

- **For an "expected," serious ADR, an increase in the rate of occurrence which is judged to be clinically important**
- **A significant hazard to the patient population, such as lack of efficacy with a medicinal product used in treating life-threatening disease**
- **A major safety finding from a newly completed animal study, (such as carcinogenicity)**

Expedited reporting of reactions that are serious but expected is not required outside the EU.

Expedited reporting is also inappropriate for serious events from clinical investigations that are considered unrelated to study product, whether the event is expected or not.

Similarly, non-serious adverse reactions, whether expected or not, will ordinarily not be subject to expedited reporting.