Vigilance

Pharmacovigilance in Clinical Trials

Sponsors of Clinical Trials **must submit reports** of unexpected serious adverse reactions to competent authorities in an expedited manner.

If you are planning on initiating a **Clinical Trial**, here are the activities you must consider to make sure you comply with Pharmacovigilance regulations.

Elaboration of Safety Management Plan

The SMP outlines the **responsibilities** of each party implicated and **defines** the **procedures for managing safety risk** associated to the corresponding drug.

Registration in Eudravigilance

Sponsors of clinical trials must submit reports of SUSARs to EudraVigilance, the **electronic system for managing and analysing information** on suspected adverse reactions to medicines in the European Economic Area (EEA).

SAE/SUSAR management & reconciliation

SAE: Serious Adverse Event
SUSAR: Suspected Unexpected Serious Adverse Reaction

- Life threatening SUSARs need to be reported within 7 calendar days
- Other SUSARs need to be reported within 15 calendar days

DSUR elaboration & submission

DSUR: Development Safety Update Report

The DSUR must be annually submitted to health authorities among ICH regions

Keep in mind that, depending on where you decide to conduct your clinical trials, you will need to consider **local requirements** that **may apply to each territory.**

No matter where you are planning on conducting your Clinical Trial.
At Asphalion we can provide you with worldwide support.

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