Pharmacovigilance & Safety Reporting Guidelines

Purpose

The King's Health Partners—Clinical Trials Office (KHP-CTO) PV policy describes responsibilities and activities for the Sponsor and Investigator related to Pharmacovigilance & Safety Reporting.

The policy applies to all trials involving Investigational Medicinal Products (IMPs), as defined in the Medicines for Human Use (Clinical Trials) Regulations, which are sponsored or co-sponsored by one or more of the KHP-CTO Partner Organisations .

Standard Definitions

Adverse Event (AE) Any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are **not necessarily caused by or related to that product.**

Adverse Drug Reaction (ADR) Any untoward and unintended response in a subject to an investigational medicinal product which is **related to any dose administered to that subject**.

Serious Adverse Event or Reaction (SAE/SAR)
An adverse experience that results in any of the following outcomes:

- death
- a life-threatening adverse experience
- inpatient hospitalization or prolongation of existing hospitalisation.
- a persistent or significant disability or incapacity
- a congenital anomaly/birth defect

Important Medical Event (IME) An adverse event that does not meet one of the Serious Criteria but is, in the opinion of an Investigator, a significant clinical occurrence or may lead to one of the above outcomes if left untreated.

Related Topics

Related topics detailed in the policy include:

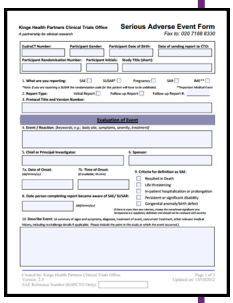
- Pregnancy safety reporting
- Urgent safety measures
- Ongoing safety evaluations of any IMP
- Annual Safety Reports
- Clinical Governance/Risk Management

Expedited Reporting

Unless specified otherwise in the protocol, **all Serious Adverse Events/Reactions, Pregnancies and IMEs** must be reported to the Sponsor immediately - not more than 24 hours after clinical trial staff become aware of the event. The Chief Investigator responsible for the study should also be informed.

Where do I find the Policy & Reporting Form?

The current version of the KHP-CTO Pharmacovigilance & Safety Reporting Policy along with related forms can be found within the SAE reporting section of the KHP-CTO website:


Kings Health Partners Clinical Trials Office
Serious Adverse Event Form

www.khpcto.co.uk/SAEs/SAE_Reporting.php