

Pharmacovigilance Centre

Pharmacovigilance is a well tuned system which ensures an ongoing and systematic monitoring of the safety of a medicinal product before and after marketing authorization.

According to the WHO (World Health Organization) Pharmacovigilance is concerned with detection, assessment and prevention of adverse reactions to drugs.

In accordance with the German GCP decree (GCP-V) the investigator as well as the sponsor has the obligation to report (confirmed or suspected) serious adverse events which occurred during the conduct of clinical trials even with already approved drugs to the competent authorities. The objective is to discover adverse effects early on so that measures can be taken to minimize the risk with respect to patient safety.

The Clinical Trials Unit of the Pharmacovigilance Center comprises medical doctors and members of the Data Management Department and supports sponsors/clients during the conduct of clinical trials regarding tasks previously agreed upon.

The Pharmacovigilance team fulfils documentation and notification obligations mainly for Investigator Initiated Trials (IITs) which are conducted at the University Medical Center Freiburg. This includes in particular:

- Documentation of serious adverse events (SAEs)
- Notification obligation (according to §13 GCP-V) of Suspected Unexpected Serious Adverse Reactions, i.e. expedited reporting of SUSARs

In order to run the SAE management efficiently and to meet reporting deadlines (e.g. SUSARs have to be reported within 15 days to the competent authorities), not only the necessary professional expertise is required but also an appropriate data capture system. Thus, the Clinical Trials Unit has been using the electronic tool eSafetyNet for SAE data capture since 2011. eSafetyNet fulfils all requirements in compliance with ICH E2B and is used in particular for clinical trials which are conducted in accordance with the German Medicines Act (AMG).

The Pharmacovigilance Center provides the following services for you:

- SAE management for all national clinical trials
- SUSAR reporting via CIOMS form
- Preparation of Annual Safety Reports and other periodical reports / listings
- Development of pharmacovigilance plans
- Customazation of SAE forms
- Professional consulting services regarding the chapter 'Pharmacovigilance' in clinical trial protocols

In addition, our medical doctors, who closely interact with our Data Management Department, provide expert MedDRA coding for adverse events and WHO DD coding for medication.

The Pharmacovigilance Team:

Regina Engel Dr. med. Olga Grishina Dr. med. Nicola Wiechmann Dr. med. Sandra Baumgartner

If you are interested or if you have any questions please write an e-mail to zks-pv@uniklinik-freiburg.de or call our study hotline at +49 761 270-77780 (Monday to Friday, 8 a.m. to 5 p.m.).
--