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Pharmacovigilance Services

Why Pharmacovigilance?

Pharmacovigilance (PhV) is the fundamental cornerstone for ensuring patient safety in clinical development and post authorization both for medicinal products as well as for medical devices. Accurate and responsible monitoring of adverse events/reactions and risks observed during clinical development as well as post authorization is mandatory and in the best interest of patients, investigators, subscribers, payors and sponsors. However, resources and/or specialist know-how of sponsors and marketing authorization holders (MAHs) might be limited, or company-internal PhV already suffering from highly stretched resources.

What We Can Do for Our Customers

PPH plus PhV professionals are trained physicians and have sound knowledge and understanding of relevant PhV regulations and guidelines and a solid expertise of processes and procedures thereof. This applies to medicines and medical devices in clinical research as well as marketed products.

PPH plus PhV specialists are prepared to take over PhV responsibilities for a study or an entire development program and to closely cooperate with dedicated departments of the sponsor. PPH plus can contribute to the preparation and revision of company core safety information and associated product labeling. Our PhV experts do provide reliable, balanced information for the effective assessment of the benefit-risk profile of the sponsor product.

In particular, PPH plus PhV specialists are prepared to assume responsibility – in total or in part – for the following tasks and duties in clinical trials as well as post-authorization both for medicinal products and medical devices:

- Review SAE reports from clinical trial sites with specific support for investigators and preparation of case narratives
- Assist with review and preparation of safety section(s) of Investigator's Brochures, study protocols, informed consent forms, and clinical study reports
- Establish and moderate Data Safety Monitoring Boards in clinical trials

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- Take over Drug Safety Officer function for clinical studies
- Evaluate adverse events/reactions emerging from clinical studies or post-authorization surveillance
- Review and interpret safety data for clinical study reports or other regulatory documents
- Participate in the development of safety surveillance and risk management plans
- Prepare and provide PhV training (e.g., clinical trial sites, project team) as needed
- Perform medical review of post-authorization individual case safety reports (ICSRs)
- Collaborate with Clinical Research Units, Medical Affairs, PhV colleagues and applicable functional specialists to identify, evaluate and manage safety signals
- Provide support for internal and external PhV audits
- Assist with literature review for identification of adverse drug reactions and safety signals
- Interact with sponsor's business partners in accordance with applicable Safety Data Exchange Agreements
- Review of SAE medical coding

Customer Benefit

Due to the scientific qualifications and expert knowledge PPH plus PhV specialists are ideally suited to act as perfect link between the sponsor and the involved trial sites. Our specialists ensure tight contacts between sponsor and trial sites thus improving the flow of information and the detection, communication and resolution of safety issues of medicinal products and medical devices in clinical trials. Once the products are on the market continuous safety monitoring can be provided by PPH plus either on a short- or long-term basis.

PPH plus PhV professionals effectively support sponsors in the prevention of drug-induced human suffering and help to avoid sponsor's financial risks associated with inappropriately managed safety profiles.