



Fact Sheet

Medical Monitoring

Why Medical Monitoring?

Substantial medical know-how is indispensable for both entire clinical development programs and individual clinical trials. It is essential to obtain medical input into the design and evaluation of study programs and protocols. Medical monitoring by an experienced research physician ensures the clinical integrity of trial results and the safety of participating trial subjects.

Unforeseen safety problems emerging during a clinical study can demand a slow-down or halt of the trial and may increase trial costs by undue extensions of scheduled timelines. Professional safety signal identification and tracking is important, thus generating a basis of hard data for ongoing and future studies and at the same time increasing the body of evidence. Medical Monitors may anticipate in advance safety issues and adverse events and manage these complications once they arise.

What We Can Do for Our Customers

PPH plus Medical Monitors provide support to sites by - answering investigator questions regarding appropriate interpretation/application of the study protocol and give advice regarding appropriate medical management of subject emergencies. Medical Monitors ensure that safety measures during a study are in place and are functioning.

Furthermore, the assigned Medical Monitor assumes medical leadership of the clinical trial project team.

The PPH plus Medical Monitor takes over complete or partial responsibility for the following tasks and activities:

- Medical review and/or writing of program/study documents including, e.g., the clinical development plan, Investigator's Brochure, study protocol, informed consent form, and final study report
- Significant contributions to clinical development plans and protocol design
- Medical input into statistical analysis plans
- Study-specific training of staff and investigators



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- Medical oversight of the study including surveillance of medical issues arising during study conduct
- Study decisions regarding deviations from inclusion and exclusion criteria, dosing questions, concomitant medication requests, and emergencies
- Review of efficacy and safety data
- Medical data clarification
- Evaluation of serious adverse events (SAE) and adverse events (AE)
- SAE case narrative writing
- Literature review and evaluation

Customer Benefit

Medical management of clinical trial activities in studies is pivotal. PPH plus Medical Monitors are highly skilled in pharmaceutical medicine, thus are capable of providing substantial support in clinical development programs and specific studies. Our Medical Monitor may act as Medical Director for customers without medically qualified staff. Customers having their own medical department will benefit from our Medical Monitors in case of capacity issues. In both cases, responsible medical leadership in a given project/study is guaranteed through the involvement of PPH plus expertise.