

Performance in Clinical Trials

Pharmatio GmbH with new Portfolio

Summary

Pharmatio GmbH, already established in the monitoring and site liaison of clinical trials, has restructured its services. With Clinical Trial Liaison, the sponsors of clinical trials can ensure the patient recruitment and effectiveness of their clinical trials. The Clinical Trial Task Force masters difficult or unforeseen challenges in clinical trials, and High Quality Monitoring ensures that Pharmatio ensures all-time inspection readiness of clinical trial sites.

In our daily work we often experience that the sites of clinical trials fail to recruit the required number of patients or do not recruit them quickly enough. In addition, the performance of clinical trials often falls short of expectations. It must also be understood that for medical practices and clinics working on clinical trials is usually an additional business. If, therefore, the processes of clinical trials planned by the sponsors do not match the procedures of the trial sites, the study teams are only hardly motivated to actively participate in a clinical study.

We face these challenges with Clinical Trial Liaison (CTL). Our staff first analyses the recruitment potential of the trial sites and all the processes of a clinical trial with regard to their practical feasibility. They then implement the resulting recruitment strategy and the study processes at the trial sites and supervise the study teams during implementation. In this way, an effective partnership with the study teams is established, which ensures the success of the clinical trial.

Usually a CTL project is started to solve problems that are already obvious. If, however, such a project is already started in the planning phase, costly amendments to the clinical trial protocol can be avoided and valuable time and additional costs can be saved.

Our Clinical Trial Task Force (CTTF) is at the disposal of clinical trial sponsors and contract research organisations to master challenges that can't be planned for out of budget reasons or which are unforeseeable. Among others this can be the preparation of a trial master file, the preparation of problematic trial sites for an audit or an inspection or the balance of interests between the sponsor and a clinical research organization (CRO).

Finally High Quality Monitoring (HQM) is the monitoring of clinical trial sites at the highest quality level. The goal of High Quality Monitoring is all-time "Inspection Readiness" of the trial sites participating in a study at any time. This is achievable through sophisticated processes, transparent and complete reporting and the implementation of appropriate Corrective and Preventive Actions (CAPAS) in case of deviations from the planned studies conduct.

About Pharmatio

Pharmatio has experts with many years of experience in the operational conduct of clinical trials at its disposal, which are best networked within clinical research, and can provide teams for the successful accomplishment of the described tasks within a very short time. Pharmatios experts are familiar with the current regulatory requirements and work in the projects either according to Pharmatio's own SOPs or those of its clients.

Contact: Robert Dannfeld, Managing Director Pharmatio GmbH, Haselweg 1, 22880 Wedel, Federal Republic of Germany

T: +49-4103/1 68 28, M: +49-171/31 22 757, F: +49-4103/1 89 90 31, E: rdannfeld@pharmatio.com

Receive further information at: <http://www.pharmatio.com>