MONITORING SIGNIFICANTLY INFLUENCES THE QUALITY OF THE STUDY

Monitoring ensures and documents the compliance with the investigation plan, `Good Clinical Practise´ (GCP) and legal regulations.

A distinction is made between `online monitoring´, which is applied in electronic CRF (eCRF), and on-site monitoring in the study-centres, which is carried out by our experienced Clinical Research Assistants.

The online monitoring is performed within 48 hours. Here, incomplete datasets or incorrect entries are identified and edited with the study centres. Queries are made via the communication system of the electronic data base, via email or by phone, in order to complete the data promptly. The advantage is that the study doctors in charge have all the patient information at hand and the datasets can be edited quickly.

On-site monitoring is planned together with you. We can take over the following services:

- Choice of suitable study sites
- Compiling of individual manuals to carry out the monitoring
- Selection visits
- Initiation visits
- Routine visits
- Close out visits
- TMF-compilation and/or update
- Briefing of study centres regarding the study and the eCRF
- Comparison of study files with source data
- Query management
- Monitoring of SAE documentation
- Ensuring of filing in accordance with GCP
- Prompt reports after every visit
- Preparations before audits

Good communication is of great importance and ensures that our CRA are constantly in close contact with the study centres and are also available for any queries between the visits. Any special developments are passed on to the principal investigator and the sponsor to ensure that they are informed about current study developments.