

## Monitoring

The Monitoring division provides the following services:

- Preparation of monitor manuals / instructions
- Contact point between sponsor and trial centre
- Initiation of trial centres
- Regular interim visits at trial centres
- Verification of the collected data at the trial centre
- Close-out visits
- Conducting of training courses

The clinical monitor undertakes the continuous supervision of the monitoring of a clinical study at the clinical trial centre. Usually the monitor works at the trial site and represents the link between the sponsor and investigator. The monitor's main tasks are to support of the investigator, verify study data collected and ensure that current regulations and legislation are adhered to by all participants in the trial centre. Our monitors go through special internal training at Clinical Trials Unit, supplemented by well-known external organisations and have either a medical or scientific background. Regular further and advanced training also takes place by means of training courses at the Clinical Trials Unit, the use of further training possibilities at the University Medical Center itself and attendance at relevant national and international specialist conferences, as well as in cooperation with sections. Within the framework of their activity the monitors provide a considerable contribution to the implementation of ICH-GCP regulations through the conducting of clinical trials.

The spectrum of activities of Monitoring include among other things:

- Selection of trial centres
- Creation of network plans for monitoring
- Monitoring visits to initiate centres
- Conducting of training courses at the trial centre
- Preparation of trial documentation and trial substances
- On-site monitoring visits (interim and close-out visits)
- A "Hotline" for queries from the trial centres
- Interim reports regarding the status of the clinical trial
- Guarantee of the forwarding of SAEs in due time