

Study Nurse

In order to optimise and ensure the quality of conducting clinical trials only nurses are employed at the Clinical Trials Unit. They are furthermore qualified by certified courses for study nurses and are familiar with the national and international rules of clinical trials – Good Clinical Practice (ICH-GCP) – and apply them in a directed way.

The business activities of the study nurses could be requested over the entire clinical study or modular.

In the preparatory phase, study nurses work closely together with the investigator and the project coordinators of the Clinical Trials Unit. Their duties include:

- Updating und ongoing support of the investigator site file
- Preparation of the documentation necessary for the conducting of the clinical study
- Administration of routine correspondence

In the conducting phase, the study nurses are responsible for the coordination of study progression according to specific guidelines:

- Appointment coordination and registration of the appropriate diagnostic measures
- Assistance in the maintaining of patient diaries/questionnaires (e.g. score-investigations)
- Administration and application of study medication
- Determine of study based data, e.g vital parameters, ECG
- Production of the necessary laboratory samples and their appropriate treatment, storage and transportation
- Prompt documentation in the CRF
- Support of the investigator in the keeping of registration deadlines for SAEs
- Preparation and assistance in monitor visits

At the study end the study nurses are responsible for:

- Return of earmarked materials to the sponsor
- Examination of study documentation for completeness
- Preparing and supporting of the close-out visits