

The Medical Services division is responsible for:

- Project supervision from the planning phase up to the completion of clinical, non-interventional and epidemiological trials involving drugs as well as medical devices
- Supervision of and contribution to cost calculations
- Preparation and review of relevant study documentation such as clinical trial protocols, protocol amendments, patient information leaflets and informed consent forms
- Supervision of the completion and submission of applications with ethics committees and regulatory authorities
- Performance of medical bedside activities in clinical trials
- Provision of drug safety expertise within the framework of the SAE-Management-Center established at the Clinical Trials Unit
- Medical monitoring and clinical on-site monitoring
- Contribution to data management and statistical analysis
- Preparation of interim reports and integrated study reports

The state-of-the-art performance of clinical, non-interventional and epidemiological trials in adherence to all national and international standards requires the availability of a team of adequately trained and experienced professionals covering all relevant disciplines. In this context, the Medical Services division with its project physicians covers all medical aspects of industry-sponsored as well as of investigator-initiated studies from study initiation to close-out. Already during the planning phase the Medical Services division provides scientific input in order to establish a project-tailored study design which fulfils the requirements of international guidelines and regulations. After the key design issues are clarified, the division takes over the lead in the preparation of relevant study documentation such as study outlines, study protocols, patient information leaflets and informed consent forms. When approached by investigators or industrial sponsors with draft versions of study outlines or study protocols the division provides the client with scientifically and regulatory sound and detailed recommendations.

The obtaining of approvals from ethics committees as well as from regulatory authorities on a national and international level involves highly regulated and bureaucratic processes. The Clinical Trials Unit provides all resources necessary to apply for such approvals. In this context, the Medical Services division supervises the completion of all relevant regulatory documentation as well as their submission to the responsible ethics committees and competent regulatory authorities. The division can also take over other legally required communications with ethics committees and regulatory authorities during the study such as notification of participating study centres or notification of the study end. Moreover, the project physicians frequently guide and advise clinical scientists in their applications for national or international funding programmes.

By employing medical doctors, the Medical Services division is able to provide investigator capacity; thus the division not only covers the planning as well as organisational and regulatory aspects of clinical trials but also medical bedside activities under hospitalized as well as out-patient conditions. In addition, the division also provides drug safety expertise within the framework of the SAE-Management-Center established at the Clinical Trials Unit.

Apart from investigator responsibilities the Medical Services division also covers surveillance and quality assurance activities such as medical monitoring as well as clinical on-site monitoring during the conducting of a trial. Moreover, the project physicians are involved in data management and statistical analysis, especially within the framework of coding activities (e.g. coding of concomitant medication, (serious) adverse events, medical history), and provide a key role in the medical writing of interim reports and of integrated study reports.

Due to the broad experience in the planning, organisation, regulatory maintenance and practical conduct of clinical, non-interventional and epidemiologic trials the project physicians of the Clinical Trials Unit are frequently invited to give lectures at the University Medical Center Freiburg as well as at national and international conferences.