

The following services are provided by the Biometry division:

- Statistical study design and sample size calculation
- Generation of randomisation codes
- Statistical analysis plans
- Interim and final analyses
- Presentation of results in reports and publications

Statistical study planning and analysis at the Clinical Trials Unit are carried out in cooperation with the Institute of Medical Biometry and Medical Informatics of the University Medical Center Freiburg. All kinds of studies in various indication areas are dealt with. These include, among others, the following types of study:

- Medicinal product studies before and after marketing authorisation
- Studies on non-medicinal therapies and medical devices
- Diagnostic studies
- Prognostic studies
- Epidemiological studies

The involvement of qualified biostatisticians from the earliest possible stage in the planning of a study is crucial for top quality studies and valid study findings. Therefore statistical consulting plays an important role in the design stage of studies at the Clinical Trials Unit.

Statistical evaluation in interim and final analyses is performed in accordance with the clinical trial protocol and statistical analysis plan. It is carried out by highly qualified biostatisticians – an essential premise for valid study findings. The Clinical Trials Unit Freiburg is an ideal partner for these duties, on the one hand because of its highly skilled personnel and on the other hand because of its independent and autonomous status.

Statistical study planning and analysis covers the following aspects:

Statistical study planning:

- Statistical study design
- Advice on the choice of primary and secondary endpoints
- Calculation of the required number of patients to be included
- Choice of appropriate statistical analysis strategy
- Planning of statistical study monitoring (interim analyses)
- Statistical section of clinical trial protocols
- Advice on the design of case report forms (CRFs)
- Statistical analysis plans
- Generation of randomisation codes

Statistical analysis:

- Interim analyses
- Interim reports
- Co-operation with or membership in the Independent Data Monitoring Committee
- Statistical analysis, preparation of tables, graphics and listings
- Proper interpretation of study results, preparation of statistical reports and integrated clinical/statistical study reports
- Co-operation in the publication of results at scientific conferences and in scientific journals