

## Data Management

Data Management division provides the following services:

- Design and preparation of Case Report Forms (paper or electronic)
- Randomisation
- Design and set-up of the study database
- Data capture (also by internet)
- Coding
- Generation of plausibility checks and query management
- Status reports

Data Management at the Clinical Trials Unit Freiburg builds the interface between the Investigator, Monitoring and Biometry and works closely with other divisions of the Clinical Trials Unit such as Project Management and Quality Assurance. The tasks of Data Management extend from the planning phase to the final report of a study. Besides the Good Clinical Practice (ICH-GCP) Guideline national and international regulations have to be followed during data management (e.g. German drug law (AMG) and directives of the European Commission). To guarantee the validity of study data, quality assurance and quality control measures are implemented.

If documentation is performed on paper CRFs the SAS®-based data management system DAMAST is used which covers data processing from data entry up to archiving.

In addition, the Remote Data Entry System MACRO™ of the company InferMed is used for internet based data capture which enables data entry via electronic CRFs (eCRFs) directly at the trial centre.

The tasks in Data Management extend to:

- Design and preparation of CRFs
  - as paper version or as eCRF in MACRO™
- Central patient registration and randomisation by fax or telephone
- Design, set-up and validation of the study database and the data entry screens
- Data capture / data entry
- Import of external electronic data (e.g. laboratory data)
- In studies with internet based data entry:
  - Preparation of a user manual for data entry with MACRO™ for investigators, study assistants and clinical monitors
  - Training in MACRO™ for investigators, study assistants and clinical monitors
  - Hotline for MACRO™ users
  - Data verification during data entry in MACRO™
- Verification of data for consistency and plausibility by means of SAS® programs
- Preparation and processing of queries to investigators
- Preparation of status reports (concerning patient recruitment, CRFs, queries)
- Coding of adverse events, diagnoses and concomitant medication (with MedDRA and ATC or WHO-DD)
- Comparison of database against the original CRFs ("Data Quality Check")
- Closing and archiving of the database
- Transfer of study data to Biometry and assistance in statistical analysis
- Assistance in the preparation of interim reports and the final report
- Transfer of database and trial documentation to the sponsor