

## **We are happy to take over your entire data management.**

It is our aim to ensure all required processes and at the same time minimize administrative effort. In order to make financially appealing offers, we exclusively apply measures that effectively solve given problems and thereby avoid unnecessary expenditures such as over-powerful and expensive data base systems.

Your study data can either be gathered conventionally or electronically via internet (Electronic Data Capture – EDC).

Conventional data collection means compiling paper CRF (Case Report Forms) which are then entered into a data base. We can take over this task for you and can achieve high data quality thanks to double data entering.

In recent years, electronic data collection has become increasingly common, which is why we favour this in most cases. The advantage of eCRF is fast data collection with direct data presence and the possibility of faster and better data monitoring. eCRF enable immediate intervention by means of query management.

As eCRF we use a cost-effective and high-quality data base system as standard, which has proved itself in the management of more than 100.000 patients' data. The system conforms to the guidelines and offers the following features:

- Fulfillment of the ISO 14155 and GCP guidelines
- 21 CFR Part 11 conform
- In compliance with FDA
- Audit Trails
- E-Signature
- Excellent lucidity
- Logical structure
- User-friendly interfaces
- Coding of variables
- Extensive plausibility checks
- Differentiated user rights
- Implemented reports and statistics
- High-quality query management

Using a high-quality and well-functioning data base system is not the only factor for success. It is maybe even more deciding to have the experience that is necessary to logically structure a data base. In 19 years of clinical and scientific practice and in more than 1000 projects Dr. Kottmann gathered profound knowledge regarding data collection, different data base systems and statistical analyses. Thus we create user-friendly and effective data bases and focus on generating high-quality data. Thanks to optimal structures, no subsequent time-consuming restructuring of the data is necessary, so that statistical analyses can be carried out without losing valuable time.

On the basis of test data bases which we have developed, we would like to demonstrate the exceptional quality of the system!



