

## **Adequate study planning is essential for successfully completing a medical study.**

In the planning phase, medical requirements are of great significance. We offer you many impulses for your study and purposefully apply our 19 years of clinical experience. Here, we consider all required statistical issues and matters regarding data processing, in order to ensure an optimal study procedure.

It is important that the study concept also identifies the actual intention of the study, whereas redundancies should consequently be avoided. We focus on this aspect and also advise you regarding the choice of suitable parameters.

It has proved to be successful to carry out the planning phase in a team. Thus, we like to discuss and determine the study conceptualisation with the sponsor and/or the principal investigator in joined meetings. By working together effectively, the structure of the study and the necessary parameters can be determined within a reasonably short time span.

### **The following aspects need to be planned:**

- Determination of timelines
- Definition of endpoints (primary/secondary endpoints)
- Design of study protocols, respectively monitoring plans
- Compiling of patient information and declarations of consent
- Determination of sample size – if necessary
- Planning of submissions to ethic commissions
- Administrative tasks
- Conceptualisation of documentation sheets – CRFs (either conventional paper CRFs or in an electronic database)
- Finding adequate study centers
- Contracts with study doctors and coordinating
- Remuneration of study doctors / accounting modalities
- Planning of monitoring and scheduling of visits of CRA

This list, containing different sections of the fields of work, shows how work-intensive the planning phase is. Many different aspects must be considered before the study can be implemented successfully.

Depending on our agreement, we either take over single services or the entire project management.



