

ELN IT Workshop, Heidelberg 28.01.2008

## **Infermed MACRO<sup>®</sup> - Electronic Data Capture according to GCP A. Fischer (Munich / Germany)**

Clinical trials conventionally collect the patient's medical data by sending paper forms to the investigator and getting back bulks of paper. The medical information is then transferred from paper CRF into an electronic database by double entry procedure.

This method is now being displaced by EDC (Electronic Data Capture). The presentation sets EDC in contrast to paper-based data capture and recommends it as a progressive trial instrument.

The software MACRO<sup>®</sup> is a tool for capturing patient data in an electronical manner. It provides a modern and efficient as much as GCP according way of data management. Investigators at sites far away enter data in prepared eCRFs on the computerscreen. With data validation and plausibility checks the quality of data is improved instantly at inputting stage. Then data is transferred to the coordinating study center by use of a secure internet connection. With EDC the number of arising queries is extremely diminished.

MACRO<sup>®</sup> implements all requirements of good clinical practice, which every inventional clinical trial has to be compliant with. The presentation shows selected features of MACRO<sup>®</sup> that increase data quality and support trial staff by intuitive, convenient work flows.

ELN project 3 (CISC) offers MACRO<sup>®</sup> and supporting IT services to all trials conducted in cooperation with ELN.