

A Portal for Clinical Trials

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A Service for Scientific Documentation within a Research Department of a large Hospital has additional features: it may be involved in, and contribute to, the organization and management of a clinical trial, through the use of information technology. Sharing of data and information through a computer network will have an influence on time of realization, quality of data and not least on costs of a clinical trial.

For these reasons the organization of a trial based on computer networks and particularly on a Web interface will benefit to the different participants in the trial: to the experimenter who will assign randomly a treatment to a new patient satisfying entry criteria, and who will perform data entry at each scheduled visit during the trial; to the clinical monitor who will check for adherence to good clinical practice guidelines; to the data manager and the biostatistician who will administer and analyse data respectively; and finally to the project leader who will be able to check online the progression of enrolment, according to protocol schedules. These benefits will be the more evident, the higher is the number of participating centres, that need to be reached rapidly and in the simplest possible way. This project aims at the realization of a website for the management of the whole course of a randomised clinical trial. Particularly all the documentation concerning the study will be made accessible (protocol, informed consent, instructions); automatic randomisation will be available; a centralized database will allow data entry and data administration by means of different level passwords. Problems on data transmission and their privacy will be addressed.