

Internet-based integrated clinical and biological databases for therapeutic trials

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Abstract:

The French group for clinical trials Goelams initiated nearly seven years ago a competition in order to obtain a user-friendly comprehensive system allowing to build internet-based electronic case report forms (e-CRF). At that time no ready-made solution existed and an agreement was finally made with a society that proposed to create such a tool according to the Goelams' specifications.

Medcost® thus developed a platform called Webtrial which allows to build e-CRFs according to the specifications of any clinical trial. The creation of new e-CRFs is completely autonomous and can be made at any time without any need for technical support. For each patient, information regarding general data, treatment steps, biological investigations, follow-up, medico-economical studies or any other relevant point can then be entered in the central data base from any internet connection point in the world. No software requires to be installed. Access rights are protected by a login and password defining clinicians, biologists, operators or monitoring personnel. Monitoring is achieved without any possibility to modify data but allows to post queries or to definitely validate information in a color-coded easily controlled way. Moreover, extractions of all or part of the database can be performed at any time, providing tables that can be manipulated then with classical statistical software.

The Goelams group has currently more than a dozen of such trials, and this initiative has been joined by other French groups interested in oncology and hematology.