IBDIS

IBDIS launched eCRF assisted multi-Center trial in Belgium, France, Germany and Austria

Background

In April 2007, Prof. Gert v. Assche from the Department Gastroenterology, the University of Leuven Hospitals and Nikolaus F. Pedarnig, IBDIS project manager at UNIDATA GEODESIGN, started to collaborate on a clinical trial project: An Open Label, Prospective, Multi-Center Trial, on the Effect of Anti-TNFα Chimeric Monoclonal Antibody (Infliximab, Remicade®) on Inflammatory and Fibrous Lesions in Patients with Intestinal Crohn's Disease.

At a very early stage of the project Prof. van Assche decided to derive advantage from an **electronic case report form eCRF**. Considering, that this is a multicenter trial (University of Leuven Hospitals, University of Lille, University of Vienna, Technical University of Munich), easy access for each user of the eCRF had to be guaranteed and interaction of the software with heterogeneous information technology infrastructures at the centres was required. Moreover, the software needed to be integrated into the workflows of the clinical routine. So at this stage the IBDIS team began to design a web based eCRF (Figure 1).

In autumn 2007, the eCRF software reached its prototyping phase. The eCRF was built with the IBDIS modules general patient data, anamnesis, the security features SAE/SAR/SUSAR, complications and risk factors, location, administration of medication and an eCRF controlled course of visits. Go-LIVE of the eCRF was in december 2007.

GCP and data security

The development of an eCRF necessitates a high attention on **prevention of unauthorized access, quality of data** and **data management**. Following the guidelines of good clinical practice **GCP** and the UNIDATA/IBDIS standard operating procedures, the following concept of rights and roles was used (Figure 2).

IBDIS eCRFs are equipped with two concepts concerning **quality of data**. The first method is an active one and integrates consistency checks for forms and data fields, which support the user during the process of data capture (e.g. value out

Figure 1. Screen shot from visit schedule of the web based IBDIS eCRF

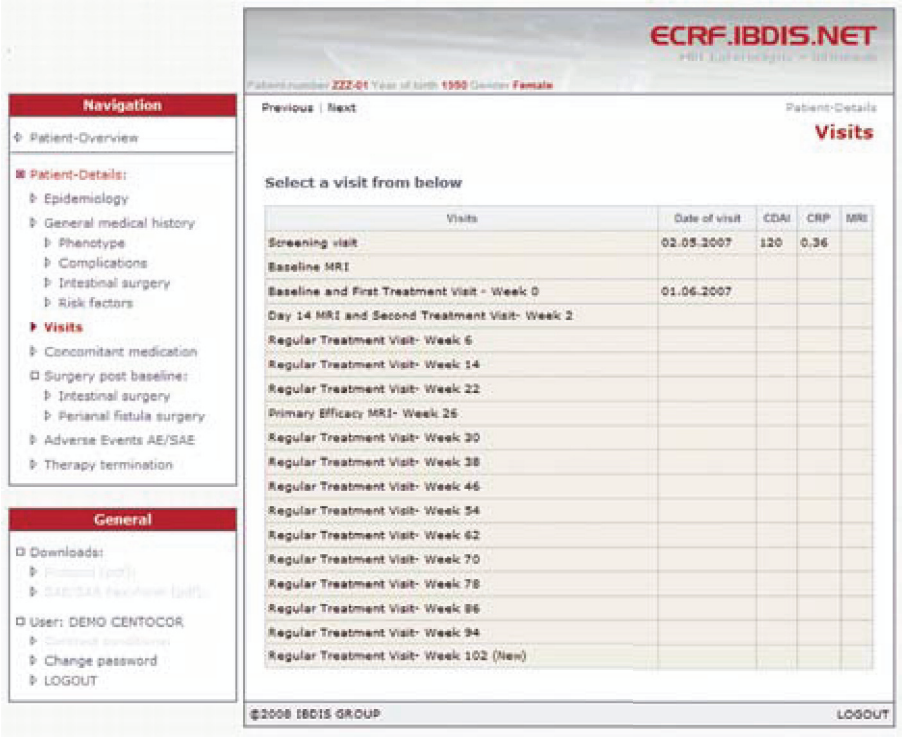


Figure 2. Matrix of rights and roles

Electronic data capture						
	Centre 1			Centre 2		
	User 1	User 2	User 3	User 4	User 5	User n
User 1	R W					
User 2		R W				
User 3			R W			
User 4				R W		
User 5					R W	
User n						R W
CSA1	R W	R W	R W			
CSA2				R W	R W	R W
MON	R	R	R	R	R	R
MPA	R W	R W	R W	R W	R W	R W
UGA	-	-	-	-	-	-

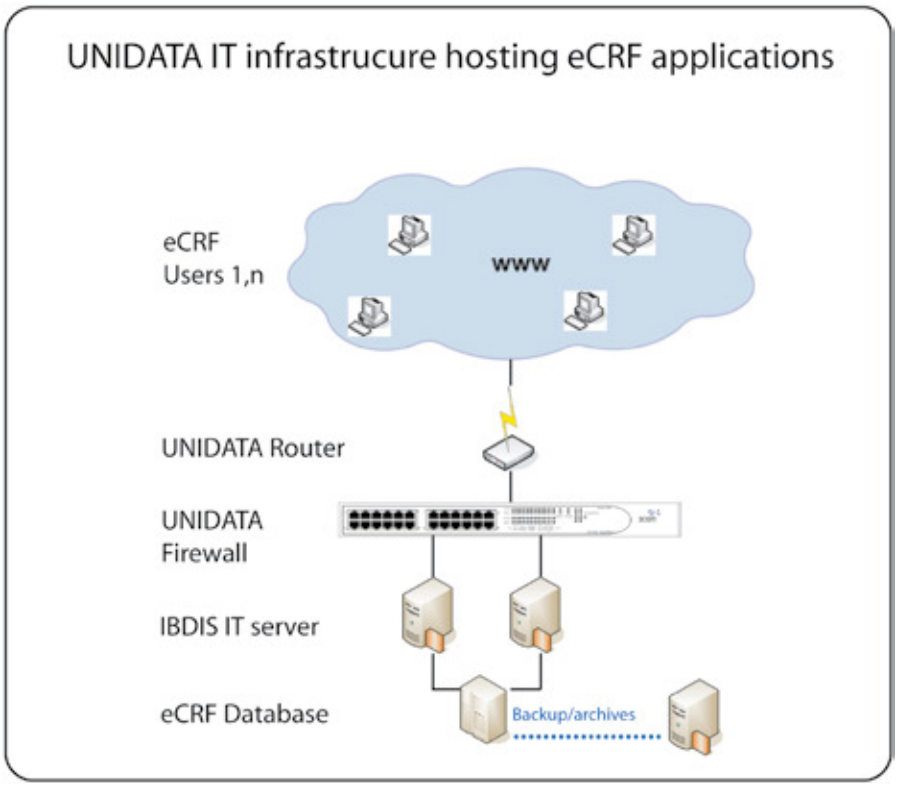
CSA1 Clinical site administrator centre 1
MON Clinical monitor
MPA Medical project manager
UGA UNIDATA GEODESIGN administrator
R Read data, W Write/modify data

of range, date not allowed prior or after another date or situation, entry of non-numeric data not allowed). The second method supports the clinical monitoring. The monitor role includes checking the data content, raising queries in case of missing, wrong interpreted, mistyped or illogical data, supporting source document verification, freezing and thawing (unlocking) data and controlling the flow of the trial. These issues improve the quality of data and of the whole flow of the trial.

According to European and national legal guidelines and restrictions, only anonymised or pseudonymised patient data can be stored at extramural data centres. Patient data of this eCRF is stored at the validated UNIDATA GEODESIGN IT centre in Vienna, Austria, using state-of-the-art technology, methods, tools, services and encryption standards. (Figure 3):

NIKOLAUS F. PEDARNIG,
CEO UNIDATA GEODESIGN
nikolaus.pedarnig@ibdis.net

Figure 3. IT infrastructure of UNIDATA's eCRF department.



CALL FOR ECCO FELLOWSHIPS, ECCO GRANT AND TRAVEL AWARD APPLICATIONS

Deadline: October 1, 2008

ECCO has established Fellowships, Grants and Travel Awards to encourage young physicians in their career and to promote innovative scientific research in IBD in Europe.

Fellowships are created for young individuals aged <40 years, who submit an original research project which they wish to undertake abroad in a European hosting laboratory and/or department. The department should have accepted to host and guide the Fellow for the duration of the Fellowship (one year) and are responsible together with the Fellow for the successful completion of the project. Fellowships are awarded a total amount of 30.000 Euro.

ECCO Grants are created to support good and innovative scientific, translational, or clinical research in Europe. The guidelines of ECCO Grants are very similar to those of the Fellowships, with the exception that the research is typically undertaken in the institution of the applicant. ECCO Grants are awarded 15.000 Euro each and will also be announced during the ECCO annual congress.

Travel Awards were established in 2007 as an opportunity for young investigators to visit different ECCO centres in Europe, to learn scientific techniques or to observe clinical practice with a specific project in mind.

For detailed information, eligibility and submission process on fellowships and grants please visit the ECCO Website www.ecco-ibd.eu/Scientific Committee/Fellowships and Grants.

We look forward to your application
Simon Travis,
Chair, Scientific Committee