IBDIS® – Harmonizing the documentation of IBD patients within ECCO

History

In 1999, Walter Reinisch from the General Hospital in Vienna and Nikolaus Pedarnig, founder and owner of UNIDATA GEODESIGN, started to outline the concept of a standardized documentation of IBD patients. A close co operation between science and technology was established to realize a project, which aims to result in the development of a validated and reliable catalogue of parameters relevant for scientific approaches and daily practise in inflammatory bowel diseases. The creation of a European IBD documentation standard in mind, the parameter catalogue was subjected to an interobserver assessment study and succeedingly implemented by UNIDATA GEODESIGN into a web based software. By using the worldwide web as the communication forum, code-controlled access is granted and broad availability to the community enabled.

The UNIDATA GEODESIGN website: www.ibdis.net

Partnership ECCO and IBDIS®

During the ECCO-Congress 2007 in Innsbruck the governing board of ECCO and UNIDATA GEODESIGN signed a contract about a close cooperation in future projects. IBDIS® is now a ready to use service free of charge for all ECCO members. The potential applicability of IBDIS is manifold, reaching from an electronic patient record form for clinical routine to a scientific tool for standardized patient documentation and phenotyping within the scope of clinical studies or registries.

Major goals and advantages

Using IBDIS® and its documentation tool adds the following advantages to the IBD community and all ECCO members:

- Ready to use after a long process of planning, developing, improving and testing the software including a risk analysis with identification, assessment, treatment and documentation of risks.
- Broad availability using the Internet and latest online techniques.
- IBDIS® is based on a harmonized, standardized and validated catalogue of IBD parameters.
- Continuous enhancement by implementation of technical and scientific advances, as well as repeated validation processes, now also with professional support by ECCO.
- IBDIS enables the comparison of patient populations in scientific studies based on the same documentation standard.
- IBDIS® offers a wide range of facilities to use it as an easy to adapt tool for special user requirements including registries, online surveys or EU projects.
- Several partners within the pharmaceutical industry already trust in IBDIS and the technique behind the system for their own eCRF's.
- Using a web based eCRF is a strategic move and a statement to be aware of the requirements and challenges of regulatory authorities.

How to use IBDIS®

Reliably and validly documented information on the patient is in the centre of interest of the IBDIS software application (Fig. 1).

Fig. 1. IBDIS® modules.

According to the wide range of purposes of using the IBDIS® software, UNIDATA GEODESIGN has defined 3 types of licenses:

Category I: Anonymized patient documentation with complete use of the application modules: Demographics, diagnosis, complications, risk factors, pregnancy, surgical and medical therapy. This licence uses the UNIDATA GEODESIGN server archi-

tecture and is free of charge for all ECCO members. Using this licence requires only online registration via the UNIDATA GEODESIGN website www.ibdis.net

Category II: Personalized patient documentation with full integration into the clinical routine and complete use of the application modules. Due to data security and privacy protection requirements of public authorities and the guidelines of the European Commission, UNIDATA GEODESIGN offers this category II facility. This license requires integration into the clinical centres server architecture by using a dedicated and supported IBDIS.NET server. This license brings an overall IBDIS® documentation of IBD patients by small costs. All patient data is stored at the clinical centre. The data can be anonymized for multi-centre or multinational analysis.

Category III: This IBDIS® license is used for user specified eCRF's for clinical trials from phase I to IV or for registries or named patient programs. UNIDATA's experience in consulting the pharmaceutical industry led to a number of national and Europeanwide registries on treatment in IBD as well as for other indications. Each eCRF is equipped with an integrated service tool for monitoring the data. This leads to reduced monitoring costs during the process of a study and improves the quality of data. UNIDATA GEODESIGN follows the guidelines for developing validated software applications (Fig. 2).

Fig. 2. Life cycle of planning and developing validated software according to national and international guidelines from defining user requirement specifications until roll out and maintenance periods.

eCRF features at a glance

- Easy to use data capturing.
- Standardized documentation.
- Integrated plausibility checks.
- Integrated query management and monitoring tools.
- Optimized roles and authorizations
- Worldwide availability.
- Compliance with the requirements of the FDA (21 CRF Part 11 Electronic Records and Electronic Signatures) and GAMP.

Conclusion

Quality of data

IBDIS® aims to improve the quality of data on IBD patients. The catalogue consists of more than 180 parameters that have passed an interobserver agreement analysis to evaluate scales, ranges and definitions. IBDIS® uses integrated and automated plausibility checks, a permanent Audit Trail, record retention and archiving tools to maintain the best quality of data. Every application of IBDIS® is equipped with an online support and information system (IBDIS® Knowledgebase).

Partnership

ECCO and **UNIDATA GEODESIGN** committed themselves to cooperate in the field of standardized patient documentation and to improve the quality of care of IBD patients. The outstanding experience of all ECCO members and their leadership in the knowledge about IBD and the technical Know-how provided by UNIDATA GEODESIGN are excellent bases to achieve these objectives.

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NEW!!! ECCO Fellowships and now also ECCO grants!!!

The **ECCO Fellowships** which have been established to encourage young physicians in their career and to promote innovative scientific research in IBD in Europe, have entered their second year.

During the ECCO congress in Innsbruck; Dr. Kostas Karmiris from Greece, was awarded the Fellowship for the project entitled *"Pharmacokinetic study on clinical outcome and immunogenicity of anti-TNFα agents (infliximab, adalimumab and certolizumab pegol) effective in inflammatory bowel diseases".*

The project of Dr Karmiris will be carried out at the University Hospital of Leuven, Belgium.

ECCO continues to promote its fellowships and announced to increase the number to 2 each year. Fellowships are created for young individuals <40 years, who submit an original research project, which they wish to undertake abroad in a European hosting laboratory and/or department who has accepted to host and guide the fellow for the duration of the fellowship (one year) and who is responsible together with the fellow for the successful completion of the project.

Fellowships are awarded a total amount of 30,000 Euros.

Besides the Fellowships, ECCO is now very pleased to announce **ECCO grants**, 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 own institution of the applicant.

ECCO grants are awarded 15,000 Euros each and will also be given during ECCO's annual congress. The deadline for submission of the Fellowships and the grants is December 1st, 2007.

Full instructions and application forms for ECCO Fellowships and grants can be found on *www.ecco-ibd.org* – the ECCO homepage.

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