

IBDIS® – Standardized documentation of IBD comes true

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IBDIS – a tool for ECCO

By contract ECCO and UNIDATA GEODESIGN set out to stimulate the harmonization of data registration in the field of IBD by using IBDIS (Inflammatory Bowel Disease Information System) on the medical information from individual patients. As a catalogue of standardized and validated parameters related to IBD, IBDIS reconciles the challenging demands from ECCO and potential third party users, such as partners from pharmaceutical industry or regulatory authorities. Accordingly, IBDIS is available via internet and designed to support several potential applications. From a ready-to-use tool for scientific analysis to an electronic patient record **ePR** with integration into the clinical routine, or an electronic case report form **eCRF**, as applied in clinical trials, registries, biobanks or health economic studies, IBDIS poses the documentation standard which is easily to adapt to the customers' demands. For the use of IBDIS individual ECCO members or third party members may either apply for a license at ECCO or UNIDATA GEODESIGN.

Who can apply for an IBDIS license?

UNIDATA GEODESIGN developed three categories of online-tools to meet the needs of the IBD community:

1. IBDIS Standard Software for individual ECCO members.
2. IBDIS ePR Software for individual ECCO members.
3. IBDIS eCRF Software for the pharmaceutical industry, regulatory authorities or investigator-initiated studies of individual ECCO members.

Dependent upon the intended application and the user's specific requirements IBDIS is provided either as ready-to-use standard software or may be adapted accordingly. Figure 1 displays potential licensees, their demands for standardized patient documentation and the respective IBDIS Package which fits their needs.



Nikolaus F. Pedarnig (left) – General manager of UNIDATA and co-founder of IBDIS, Miguel Gassul – President of ECCO, Daan Hommes (right) – Chairman Scientific Committee, during a meeting of the ECCO governing board in July 2007 in Vienna.

Are there costs for licensees?

The IBDIS Standard Software will be free of charge for individual ECCO members. Individual ECCO membership will be applicable in 2008. However, licensees incur project fees for IBDIS ePR and IBDIS eCRF composed of a fixed start-up amount and maintenance costs. Projects using IBDIS requested by ECCO or its members shall be reviewed and approved by ECCO's scientific committee. All activities undertaken shall be in accordance with any and all applicable law and regulations, as well as general accepted international ethical standards. Figure 2 shows the relationship between the licensee, the costs and the location of data storage.

Who owns data registered by IBDIS?

An adequate confidentiality agreement

between UNIDATA and the party requesting any IBDIS package shall be in place. Licensees acquire sole ownership of the captured data. Also any and all rights to inventions and discoveries that may be conceived or generated in connection with an IBDIS project shall be solely owned by the licensee.

Role of UNIDATA GEODESIGN

UNIDATA GEODESIGN acts as the owner of the IBDIS software, performing user required adaptation of the software, maintaining and supporting the proper functionality and availability of the application. In case of user requirements for adaptation of the standard software, UNIDATA GEODESIGN consults during the planning process and implements modifications.

Questions and answers
What is the difference between the IBDIS Standard Software and the IBDIS electronic Patient Record Software?

The IBDIS standard software is a free tool to build IBD-databases for individual ECCO members. Anonymous data is stored at the UNIDATA GEODESIGN facilities. The IBDIS ePR Software is adapted from the IBDIS standard software and designed to be integrated into the clinical routine setting. IBDIS ePR records personalized data stored at servers at UNIDATA Geodesign or at the clinical site.

Both licenses enable electronic data capturing about **epidemiology, location, phenotype, course of disease, complications, intestinal surgery, comorbidity and risk factors, pregnancy and therapy.**

What are the first steps to gain access and use the IBDIS Standard Software?

Access <https://documentation.ibdis.net> with your internet browser, click the "Getting Started"-button and follow the instructions on the screen.

Is there a demo-license available of the software?

UNIDATA GEODESIGN grants access to a limited demo license for all, who submit the demo License application form and the confidentiality agreement, both available at <https://documentation.ibdis.net> to UNIDATA GEODESIGN via fax.

Is the IBDIS Standard Software free for everyone?

The free use of the IBDIS Standard software tool is restricted to individual ECCO members. ECCO will grant individual membership in 2008.

Who is the owner of the data?

Every licensee has full ownership of his/her data.

Where are IBDIS-registered data stored?

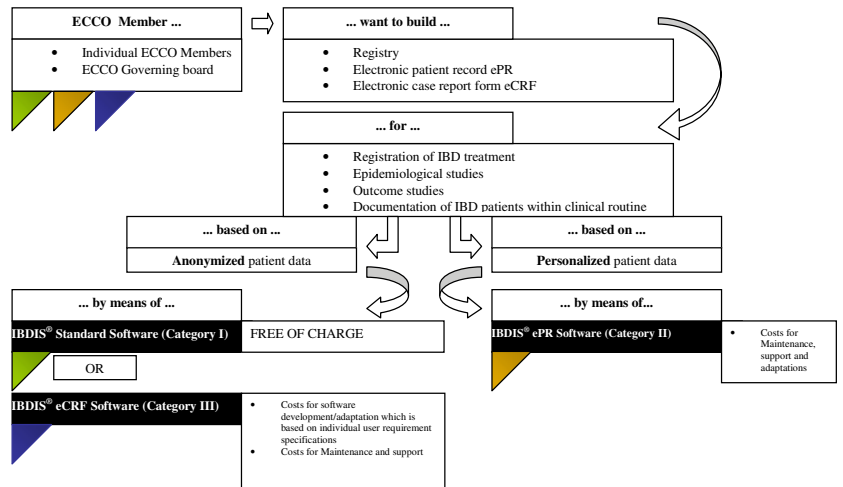
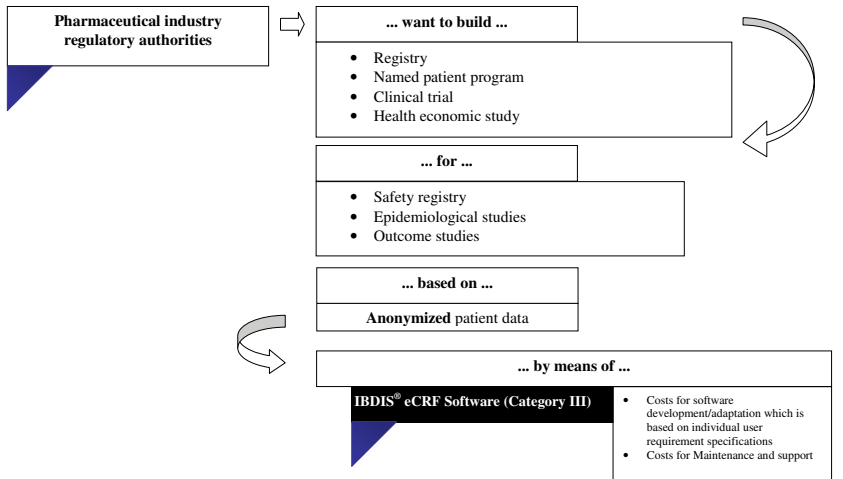
The anonymous information registered by the IBDIS Standard Software is stored at the validated UNIDATA servers in Vienna, Austria. According to national or international law the database on personalized information captured by IBDIS ePR may be kept inside the respective clinical site. Data from IBDIS eCRFs are stored according to the third party member's request.

Does licensee acquire ownership of the IBDIS software?

No, the licensee acquires the right to use the software restricted by the terms of the confidentiality agreement and the software license agreement. The software itself remains property of UNIDATA GEODESIGN.

Where can I get more information about the IBDIS project and the software tools provided by UNIDATA GEODESIGN?

Please contact UNIDATA GEODESIGN or ECCO for additional information or access the corporate website: <https://documentation.ibdis.net>

Figure 1a: License for individual ECCO-members

Figure 1b: License for pharmaceutical industry and regulatory authorities

Figure 2: Licenses, costs and ownership of data

		License		
		IBDIS® Standard Software Category I	IBDIS® ePR Software Category II	IBDIS® eCRF Software Category III
Licensee/ownership of data	ECCO Member	Anonymized data Ready-to-use Free of charge Server located at UNIDATA GEODESIGN	Personalized data Costs for maintenance and support Ready-to-use Server provided by clinical site or UNIDATA GEODESIGN	Anonymized data Costs for maintenance and support Costs for software development, adaptation, consulting Server provided by clinical site or UNIDATA GEODESIGN
	Pharmaceutical industry/regulatory authority			Anonymized data Costs for maintenance and support Costs for software development, adaptation, consulting Server provided by licensee or UNIDATA GEODESIGN