

## European Society for Immune Deficiencies DATABASE:

Summary by Carrock Sewell; updated March 2005 by Helen Chapel

**Purpose:** an online database system for the collection and exchange of data relating to individual patients with primary immune deficiency diseases ("PID").

### Data collection:

- The database only stores anonymised data
- The codes for each patient are kept behind the local firewall or can be stored behind a dedicated firewall in Freiberg, whichever the centre/ national network prefer
- This facility enables the database to act as a patient monitoring system for the local clinic, generating physician reports after each OPD visit if wished. It can also be organised by country to provide a virtual national register, though some countries (notably Spain and the US) have elected to run their national databases separately

**Fields:** The database is divided into sub-registries for each disease - CVID is one of the first to go live and about 4 new disease registries will be added each year. The most basic data on patients are called 'red fields'. Additional data is optional and is disease specific. This can be used to run your clinic if you wish, and will track everything down to individual blood tests. The level of participation is up to individual centres, but the red fields are a minimum requirement.

**Funding:** support from outside sponsors, who have specific access to a clearly defined subset of data within the red fields only for pre-defined purposes.

Centres that submit patient data are called 'Documenting Centres'. ESID will pay the Documenting Centre € 10 for the provision of each patient's "red field" data ie completion of a core dataset and €10 each subsequent year when the data is updated by the Documenting Centre. Use of the database depends on compliance by the Documenting Centre with all applicable data protection regulations by June 30<sup>th</sup> of each year. The accumulated compensation is due on September 15 of each year.

**Access:** The Documenting Centre is, and will remain, the owner of all data it has provided to the ESID Online Database. There is an ESID steering group of volunteers for each disease. Any ESID member may apply to analyse disease specific data, provided that they have the written agreement of the other Documenting Centre(s) whose data they wish to use. The relevant ESID steering group will consider all applications to analyse data, and the ensuing publications will acknowledge the centres from which data used is obtained.

ESID are entitled to make available the accumulated and anonymous "Red Field" data to the sponsors of the ESID Online Registry only for the following purposes: to enable genetic and therapeutic research across different authorized users; for genetic and therapeutic trials; for the treatment and care of patients; for the development and improvement of medication; for evaluations of epidemiologists. The receiving parties ensure to use the data for internal use only, unless they have obtained the prior written consent from ESID to publish them.

**Data protection:** The Documenting Centres agree to observe the European data protection regulations as well as the local data protection regulations. Documenting Centres will only record patient's personal data into the ESID Online Database in the Documenting Centre's local system or into the firewall protected section of the database in Freiberg. It is responsible to ensure the observance of data protection regulations on an organisational as well as on a technical level, particularly with regard to confidentiality, integrity, availability, authenticity and reliability of the collected data. In particular, each Documenting Centre will procure the necessary consent of the patients concerned to the use of the data. In the UK Multiple Ethics Committee approval has been obtained from the West Midlands office and copies of this multi-site approval can be obtained from Ms Mary Gray at the Department of Immunology, John Radcliffe Hospital, Oxford (tel. 01865 221769)

**How to use the database:** you need to sign an agreement with the Registry and be issued with a user name and password. These can be obtained from:

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