



CASE REPORT FORM (E-CRF)

Please remember that CRFs are provided by the Sponsor: to the Investigators in electronic sheets.

The electronic sheets are part of a software which allows a remote data-entry from the Centre to the Trial Data Centre through a remote informatic connection. The software includes the possibility of a limited access to the programme by authorised persons (Principal Investigator and Sub investigators). Data may be corrected (and a track of any correction is maintained) until they are locked and sent to the Trial Data Centre. After locking, data cannot be corrected peripherally by the Centre. The Trial Data Centre only may unlock and modify data on the basis of queries resolution. A print out of the electronic sheet must be available at any stage of the study. A printed final copy of the CRFs of each patient will be signed by the Investigator and filed at the Centre.

Hypernet system requirements

1)Software

- a)Windows platforms: Netscape Communicator/Navigator 4.0 or higher
Microsoft Internet Explorer 4.0 or higher**
- b)Macintosh platform Microsoft Internet Explorer 5 or higher**

2)Hardware

- a) Internet connection with a 56kbit/sec modem (or higher), ISDN or a LAN (i.e. Ethernet)**
- b) Any computer capable of running above software**