Pan-European clinical trials (EUROCORES)

Call for Project Proposals

There is a recognised need for pan-European clinical trials addressing questions that, although of limited interest to the pharmaceutical industry, have a strong impact on the quality of life and/or the morbidity and mortality of Europeans. Such questions include for instance evaluation of surgical management, preventive or therapeutic strategies, therapy of rare diseases, or new indications for old drugs. This is where the European Science Foundation (ESF) and its member organisations have a distinctive role to play and where the added value of moving from the national to the European level in such trials is self-evident.

According to its policy statement on *Controlled clinical trials* (ESF policy briefing n°13), published in May 2001 (*http://www.esf.org/ftp/pdf/2001/Espb/ESPB13.pdf*), the ESF has set-up a process to help researchers to prepare a protocol for such interventions and to find proper support through co-ordinating government, academic, institutional and charity fundings. The present call for project proposals is the first step of this process (general scheme at the following web site address: *http://www.esf.org/medical/me/ECT/ECT.htm*).

Existing European investigator networks, or informal groups of European investigators with experience in clinical research, are eligible to send letters of intent in answer to this call for proposals. These letters of intent should briefly describe the planned project according to the outline below and identify one (or more) co-ordinating centre, that is an academic team with specific experience and facilities for co-ordinating multicentre studies, data management and statistical expertise. At this stage, the network could be limited to a small number of participating institutions/investigators with appropriate expertise.

The letter of intent (see content below) should be sent **before 31 August 2001** to Dr M. Minkowski (mminkowski@esf.org) (step 2). The project proposals will be submitted to an international and independent review panel set up by ESF (step 3). Selected projects will each receive an award up to 15 000 euros to support the cost of preparing a protocol (that is meetings, consultation of statisticians, etc.) (step 5).

Finalised protocols will be submitted to the review panel (step 6), which will prioritise the projects to be proposed for funding by institutions and charities (step 7).

The letter of intent should outline briefly (maximum 6 pages) the following aspects:

1. Name, CV and up to 5 major publications of the proponents representing the network of investigators
2. List of (core) institutions/investigators (from more than two European countries) who have agreed to participate, with their affiliation, address and e-mail.
3. Name and a summary of previous experience of the co-ordinating centre(s) in conducting clinical trials.
4. Outline of the planned trial
   - 4.1 Objectives
   - 4.2 Rationale, including a state of the art review based on a systematic review either already published or done on purpose, supportive references and an account of ongoing clinical trials.
   - 4.3 Disease(s)/condition(s)
   - 4.4 Settings where the patients will be recruited
   - 4.5 Intervention(s) to be tested
   - 4.6 Mode of supplying with tested and control drug(s) or devices for the study
   - 4.7 Type of design and randomisation process
   - 4.8 Sample size (order of magnitude)
   - 4.9 Duration of the study
5. Potential benefit of expected results in terms of public health and/or knowledge improvement.
6. Process by which ethical issues will be dealt with.
7. Explanations of the reasons why the private sector is not interested in supporting this research.
8. An estimate of the final budget of the trial.

Submission format:

Letter of intent (including CV, etc) should be emailed in 1 attachment only in pdf or rich text format.
The subject of the message will be: Application to ECT.
All margins should be at least 3 cm and headers and footers not less than 2 cm.

For more information contact:
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