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Profile

The European Ethical Review Committee

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This series of brief profiles is intended to provide an introduction to a number of organizations, of widely differing character, which each in their own way contribute to safety in medicine and health care.

The European Ethical Review Committee, which concerns itself with the standards applicable to clinical trials with medicinal products, was established in 1977 and, as the name suggests, draws its membership from the countries of Europe. Its structure comprises a Board and panels of experts representing internal medicine, clinical pharmacology, general practice, nursing, legal and lay persons. Board members attend all meetings and indeed the structure of the Board is such that it constitutes an ethics committee in FDA terms in its own right. Full meetings normally comprise the Board and a member drawn from each of the consultant panels, the members of which are often selected in recognition of their particular expertise in the area of the protocols to be reviewed.

In the main, the EERC reviews protocols for multi-centre clinical trials, usually within Europe and sponsored by pharmaceutical companies. EERC standard operating procedures require the sponsoring company's representative and/or the clinical investigator to be present at its meeting to present the protocol and receive comments on it in person. This dialogue between the Committee and pharmaceutical companies is an especially valuable feature, since amendments to the protocol can be agreed at the meeting and the assessment of protocols is facilitated. At the end of the meeting, protocols are either accepted as they stand or, more commonly, accepted with amendments and a certificate of approval is issued. Less commonly, a protocol is referred back to the pharmaceutical company and a certificate is not given.

The Committee meets at the University of Leuven, Belgium, every six weeks and occasionally in London. In the thirteen years of its existence, the EERC has met 96 times to review 530 protocols from 23 different pharmaceutical companies. Its procedures require it to hold a general meeting annually at which all companies

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which have submitted protocols are requested to report on the progress of their studies. This ongoing review is modified according to the protocol; the Committee frequently requests a report after three or six months if the circumstances dictate this.

The Board comprises a medically qualified Chairman (currently from The Netherlands), a Vice-Chairman (Internal medicine, Belgium), a secretary (Toxicology, France), a Clinical Pharmacologist (United Kingdom) and two lay members (Belgium and United Kingdom). The consultant panels comprise members from the following countries:

Clinical Pharmacology:	Federal Republic of Germany (2), U.K. (3);
Internal Medicine:	Norway (1), Italy (2), U.K. (2);
General Practice:	France (1), U.K. (3);
Law:	Belgium (2), U.K. (1);
Nursing:	France (1), Italy (1), U.K. (1).

Members of the Committee are elected for a period of three years and may be re-elected if they so wish, provided (in the case of the professional members) that they are still exercising their profession. The Committee was initially established to respond to the need for ethical review in Europe at a time when few ethics committees existed within countries. It is to the credit of the Pfizer company that it recognized this need and played an important supportive role in enabling the Committee to become established. With the subsequent growth of ethical review committees in the countries of Europe, the role of the EERC has evolved; it is today largely consulted for multi-centre studies to review the scientific and ethical aspects of protocols for clinical trials that will subsequently also be reviewed by local ethics committees. The sponsor of a trial benefits from the extensive experience of the Committee as regards multi-centre studies for the review of protocol design and in the approval of clinical investigators, drawing not only upon its collective “know how” in the conduct of such studies but also upon its knowledge of the local situation in a particular country with respect, for example, to clinical and legal practice. In this respect, the standard operating procedures require the sponsor to submit the informed consent document and patient information sheet in the languages of the countries in which the studies are to be carried out; a large part of the time during review sessions is taken up by discussion of these documents.

The EERC still stands proxy for local ethics committees in the few remaining West European centres where they do not exist, but its role is now largely that of an advisory panel prior to local ethics review in order to ensure the uniformity of protocols to be used in multi-centre studies. It is not its intention to replace local ethics committees if they exist. The Committee currently sees an expanded role for itself in clinical trials which are to be carried out in Eastern Europe where a situation obtains that is somewhat analogous to that in Western Europe when the Committee was formed. In this respect, the Committee is organizing a seminar at its Annual General Meeting this year in which representatives from Eastern Europe and those from pharmaceutical companies undertaking clinical trials there, as well as observers from the World Health Organization and the European Commission will take part.