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Issues of Concern in the Standardization and Harmonization of Psychotropic Drug Trials in Europe. Methodological Issues in Psychotropic Drug Trials (ECST)

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The objective of the ECST is to promote the exchange of ideas on issues concerning the standardisation and harmonisation of psychotropic drug trials in Europe between the pharmaceutical industry, academia, and the regulatory authorities.

Originally, the ECST acted as a sub-committee of the European College of Neuropsychopharmacology (ECNP). During the first conference organized by the sub-committee in Strasbourg in May 1991 the participants voted, however, unanimously for an independent forum with a structure analogous to the European Consensus Conferences in Munich and Zürich. It was also decided that ECST conferences will take place in Strasbourg under the name 'Strasbourg Forum' every year. ECST is, therefore, not a society and the members of the committee fulfil the role of an organising and counselling body.

The programme of the first meeting was devoted to problems related to the application of Good Clinical Practice (ethical, methodological and regulatory issues) and Health-related Quality of Life. Papers selected from this meeting were published in the International Journal of Methods in Psychiatric Research (*eg*, Bech P. Quality of life in the medical setting. *Int J Methods Psychiatr Res* 1992;2:139–144).

The second ECST conference (Strasbourg Forum II) was held on 18-19 June 1992. The discussion topics were: validity of rating scales in schizophrenia and of structured clinical interviews (SCID and SCAN), problems of placebo-controlled trials and of diagnostic diversity. Due to the importance of the papers presented at the meeting it was decided that they should be published in the International Journal of Methods in Psychiatric Research (IJMPR). However, the concept of ECST has been found to fit this journal only to some extent. Therefore, only a limited number of contributions from the 1992 Forum will appear in IJMPR.

After the 1993 Forum it was agreed that contributions presented at ECST meetings will be published in *European Psychiatry*. In the present issue of the journal we also include an extended report from the 1992 meeting.

The third ECST Strasbourg Forum was held in June 1993. The topics discussed included: placebo responsiveness in affective disorders and schizophrenia, problems of generalization of findings and, as a follow-up of the second Forum, structured interviews in schizophrenia and depression. The proceedings of this meeting are published in this issue in accordance with the ECST concept, *ie* to give both speakers and discussants the opportunity to represent their ideas and experiences.

The outcome of the first three ECST meetings has been very encouraging. Already the first meeting established a good and constructive communication and atmosphere between representatives of regulatory authorities, clinical investigators, and industry sponsors having a common objective to achieve the highest scientific standards in clinical development and provide basic rules and conditions for the selection of better drugs for patients. Thus, although the companies develop drugs to increase effectiveness at the level of symptoms, the dimension of health-related quality of life was considered by all participants to be an important way to assess the patient's satisfaction-taking effectiveness, safety, and compliance into account. This approach, *ie* to consider the patient as the 'delighted customer' was reflected also in the ECST recommendations related to the application of Good Clinical Practice, as for instance with respect to the modalities of

informed consent needed to obtain a clear statement of the patient's willingness to participate in a trial. Moreover, ECST in accordance with the Consensus Conferences, has also recommended placebo-controlled trials in schizophrenia and suggested alternatives to reconcile ethical and methodological conflicts often encountered in their performance. The regulatory authority representatives have emphasized the importance of using rating scales with adequate inter-rater reliability. Structured interviews with the HAM-D, BPRS, PANSS, etc have, therefore, been recommended – a method often found controversial in Europe, but a requirement in the USA. The use of 'over-voice' videos to resolve transcultural inter-rater problems has also been recommended.

ECST has been established as an institution in Europe at a time, when cost-effectiveness trials followed by cost-utility trials are of increasing importance. They imply, however, the use of multiple outcome measurements, large multi-national trials, and often a large number of observations. The validity of the multi-dimensional ratings and their inter-rater reliability will, therefore, also be important discussion topics at future ECST meetings. Among the issues of concern of the next ECST Strasbourg Forum which will be held on May 25-26, 1994, health-economics will represent an important part of the conference.