

American College of Neuropsychopharmacology
Statement on Clinical Trials and Safety Registry (ies) and Databases

A registry of clinical trials of federally and privately funded health-related interventions must include information for all clinical trials (including investigator-initiated trials) conducted to test the safety, efficacy or comparative effectiveness of any drug, biological product, or device intended to treat serious illnesses, except those Phase I clinical trials, conducted solely for the safety of an unapproved drug, biological product, or device. The registry may include information for Phase I clinical trials in those situations where some efficacy component is employed. Examples of this may be the use of a putative biomarker or surrogate marker being used in conjunction with a drug being pursued for registration for an indication. Excluded, however, would be specific development of these tools, such as biomarkers/surrogate markers, where the primary intent is methods development or general scientific knowledge such as is typical of translational research where specific support of a drug undergoing registration is not being pursued.

As part of its mission, the ACNP seeks to ensure the dissemination of relevant scientific advances on diseases of the nervous system, including psychiatric, neurological, behavioral and addictive disorders. Through its official activities and the efforts of its membership, the College will work to ensure that the highest quality of science and ethics are integral to the conduct of clinical trials in our field. To this end, Members and Supporting Corporations of ACNP should agree to endorse and abide by the following principles in relationship to clinical trial registries and databases, and the timely reporting of safety and efficacy data for *all* clinical trials.

1. All clinical trials (as defined above) should be submitted for listing in clinicaltrials.gov. The information about the trial should be written in clear language consistent with the content made available to research participants in the informed consent form. In accord with Section 113 of the FDA Modernization Act, four data elements must be included in the submission to clinicaltrials.gov: Descriptive Information (including Brief Title; Brief Summary; Study Design/Phase/Study Type; Condition or Disease; Intervention); Recruitment Information (including study status re: recruiting or no longer recruiting; individual site status and eligibility criteria/gender/age); Location and Contact Information (including location of trial and/or contact information); and Administrative Data (including a unique protocol ID, study sponsor and verification date). The descriptive information, in particular, should be in lay language.
2. Articles submitted to the ACNP sponsored journal, *Neuropsychopharmacology*, reporting on the results of clinical trials, will follow the recommendations of the International Committee of Medical Journal Editors (ICMJE) in their CONSORT Guidelines, and in their other recommendations concerning the reporting of clinical trials.
3. The results of all clinical trials, regardless of outcome, must be reported in a timely manner. The results should be reported in an objective and complete manner, including a discussion of the limitations of the study.

- a. The ACNP takes positive note of the efforts of some of its Corporate Members to make available through their websites all relevant data from all Phase I-III clinical trials for drugs marketed in the United States.
 - b. The ACNP notes the high rate of negative trials in psychopharmacology especially for antidepressant and anxiolytic drugs. In the absence of a repository of data from negative trials, particularly for investigational agents, it is difficult to accurately estimate sample size requirements for clinical trials. ACNP will work with its Supporting Corporations to develop a mechanism (such as a secure website) for timely reporting of negative clinical trials data and adverse events of non-marketed drugs to be made available to investigators and sponsors of clinical trials.
4. The College supports full disclosure of relevant safety data from published and unpublished studies for all marketed drugs. This information should be updated on a regular basis as an informative and comprehensive supplement to FDA-mandated safety information. Members and Corporate Members must communicate a balance of risk and benefit information to patients (as in direct consumer advertising or in the doctor patient relationship), and in information directed to prescribing physicians and to other health care professionals. ACNP will work with others to ensure that all current and regularly updated safety data are made available to clinicians, patients and family members.
- a. The ACNP notes the development of national and regional pharmacoepidemiology databases outside North America which can be linked to patient case and death registries, as well as the limitations in the pre and post marketing databases on safety housed at the US FDA. The College supports the development of a pharmacoepidemiology database in the United States as part of the development of a national patient health information registry that includes essential safeguards for privacy and confidentiality.
 - b. The College is concerned that while direct to consumer advertising may have minimized the potential risks of some marketed drugs, some reports of patient safety issues in the press may have led to public fear of psychotropic drugs and the consequent under-treatment of patients with major mental illness. There is a clear need for greater public awareness of the risk/benefit ratio associated with all pharmacotherapy.
 - c. In conjunction with other key stakeholders (industry sponsors, federal regulators, patient advocacy organizations and the science press) the ACNP will encourage the development of clearer standards for use of scientific data in promotional activities, including direct-to-consumer advertising of psychotropic medications.
 - d. In conjunction with other stakeholders, the ACNP will encourage the development of standards for analyzing and reporting of post-marketing safety information from large databases, including the need for more case control studies.