

American College of Neuropsychopharmacology
Statement on Clinical Trials and Safety Registry (ies) and Databases
Approved by ACNP Council on November 12, 2013

ACNP views the development of treatments for serious mental disorders as a core component of its mission. All members are encouraged to promptly share results not only of formal clinical trials but also of informative clinical experience, both positive and negative, that may inform patient management and new treatment development. Members are encouraged to include clinical trial results in proposals for symposia, workshops and oral and poster communications.

When conducting clinical trials, ACNP members are expected to conform to the highest ethical standards of the field. This includes, but is not limited to, the timely reporting of safety and efficacy data for *all* clinical trials to existing (e.g., clinicaltrials.gov and principles of Section 113 of the FDA Modernization Act) and future clinical trial registries and databases; complete disclosure of real and potential conflicts of interest; and, where feasible, sharing of de-identified single subject data in order to assist in the overall enterprise of new treatment development

ACNP encourages submission of high quality clinical data to its official journal, *Neuropsychopharmacology*, for scientific dissemination. All articles submitted to the must 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. Regardless of the venue, all results should be reported in an objective and complete manner, including a discussion of the limitations of the study.

ACNP also encourages the development of 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.

ACNP will work with others to promote availability of all current and regularly updated safety data are made available to clinicians, patients and family members. The ACNP will actively encourage development of new opportunities for synergy among academia, industry, government and other stakeholders in use of clinical trial information, such as the development of standards for analyzing and reporting of post-marketing safety information, or systematic collection of case-control data. The College supports 'vertical' (between basic and translational scientists) and 'horizontal' (thematically consistent among different labs) collaborations to facilitate translating discoveries, and that creating a secure platform for data sharing may be among steps in accomplishing these goals. ACNP, through its liaison committee, encourages continuing input from all organizations and stakeholders interested in synergistic approaches to clinical trial development and development of safety registries and databases to enhance efficiency, transparency and utility of available clinical information.