

NIAAA Data Access Application

NCIG 002 -A Multisite Double-Blind, Placebo Controlled Trial of Levetiracetam Extended Release in Very Heavy-Drinking Alcohol-Dependent Patients

Title of Research Project:

Introduction

This double-blind, randomized placebo-controlled trial evaluated the efficacy and safety of levetiracetam, recruiting 130 alcohol-dependent patients, 24% women and 35% ethnic minorities, from 5 sites. All subjects received either levetiracetam or placebo and Brief Behavioral Compliance Enhancement Treatment (BBCET) intervention. Patients were stratified on clinical site, and SSRI use. No significant differences were detected between the levetiracetam XR and placebo groups in either the primary outcomes (percent heavy drinking days and percent subjects with no heavy drinking days) or in other secondary drinking outcomes.

Treatment groups did not differ on a number of nondrinking outcomes, including depression, anxiety, mood, and quality of life. The only difference observed was in alcohol-related consequences. The levetiracetam XR treatment group showed significantly fewer consequences than did the placebo group during the maintenance period ($p=0.02$). Levetiracetam XR was well-tolerated, with fatigue being the only significantly elevated adverse event, compared with placebo (53% vs. 24%, respectively; $p=0.001$).

The study sponsor was the National Institute on Alcohol Abuse and Alcoholism's (NIAAA) Clinical Investigations Group (NCIG). The data set was prepared by NIAAA and FastTrack Drugs and Biologics (the trial's Coordinating Center), and was reviewed by CSR Incorporated.

A more detailed overview of the study and main results can be found in the primary publication:

Fertig JB, Ryan ML, Falk DE, Litten RZ, Mattson ME, Ransom J, Rickman WJ, Scott C, Ciraulo D, Green AI, Tiouririne NA, Johnson B, Pettinati H, Strain EC, Devine E, Brunette MF, Kampman K, A Tompkins D, Stout R; NCIG 002 Study Group. 2012. A double-blind, placebo-controlled trial assessing the efficacy of levetiracetam extended-release in very heavy drinking alcohol-dependent patients. *Alcohol Clin Exp Res* 36(8):1421-30 PMID: 22324516.

Data Access Application Procedure and Access Policy

The NCIG 002 data set contains individual level data and is categorized as a controlled access data set. Access to the data will only be granted to approved researchers by the NIAAA Data Access Committee (DAC).

To receive access to the NCIG 002 data, the Applicant Principal Investigator must: (1) complete this Data Access Application form and (2) obtain a fully executed Data Use Agreement (DUA). The DUA is designed to define the allowable uses of the data set and to protect the confidentiality of the NCIG 002 participants. The DUA must be signed by an authorized institutional official that can legally bind the Applicant Principal Investigator's institution. This is ordinarily someone from the Applicant PI's technology transfer office. Completed applications may be submitted by email to:

Email: niaaa-dac@mail.nih.gov

(Application starts on the next page)

NCIG 002

Data Access Application

Title of Research Project:

Date of Application: _____

Applicant Principal Investigator (P.I.):

Name: _____

Affiliation: _____

Title _____

Address: _____

Telephone: _____

E-Mail: _____

Degree(s) Held: _____

Major Discipline/Field of Study: _____

May we contact you in the event that updates are made to the NCIG 002 data set and/or documentation? **Yes** **No**

Authorized Institutional Official

Name: _____

Affiliation: _____

Title: _____

Address: _____

E-Mail: _____

FWA # _____

I have read the notes on access below and will contact the DAC with any questions **Yes**

Notes on access to the NCIG 002 data:

- Only researchers who will be working on the **same Research Project under direct the supervision of the Applicant Principal Investigator (PI) at the Applicant PI's same institution** (including, but not limited to, graduate students, postdocs, data analysts, and investigators working under the Applicant PI for this project) **will be covered by this application and the DUA.**
- Researchers who will be working on the same Research Project in collaboration with the Applicant PI but are part of a **different institution** and will need direct access to the requested database are NOT covered by this application. These researchers must submit their own application and DUA to get access to the requested datasets.
- Researchers who are affiliated with the Applicant PI's institution but are working on a **separate research project** not described in this application should submit their own application and DUA.
- Individuals who may contribute to scientific papers and other works in collaboration with the Applicant PI, but do not have direct access to the requested datasets, do not need to submit an application or complete a DUA.
- If a student wishes to use this dataset in a thesis or dissertation, a faculty sponsor must submit this application and be listed as the Applicant PI.

Exhibit A

Research Project Description

Please briefly describe your research plan in the space below.

Exhibit A

Research Project Description
Continued - Extra Space