NIAAA Data Access Application

NCIG 001 -A Multisite Double-Blind, Placebo Controlled Trial of Quetiapine Fumarate XR 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 quetiapine, recruiting 224 alcohol-dependent patients, 20% women and 18% ethnic minorities, from 5 sites. All subjects received either quetiapine or placebo and Medical Management behavioral intervention. Patients were stratified on gender, clinical site, and reduction in drinking prior to randomization. No differences between the quetiapine and placebo groups were detected in the primary outcome, percentage heavy-drinking days, or other drinking outcomes. Quetiapine significantly reduced depressive symptoms and improved sleep but had no effect on other nondrinking outcomes. Results from a subgroup analysis suggest that patients who reduced their drinking prior to randomization had significantly better drinking outcomes during the maintenance phase. No significant interactions, however, were observed between reducer status and treatment group. Finally, quetiapine was generally well tolerated. Statistically significant adverse events that were more common with quetiapine versus placebo include dizziness, dry mouth, dyspepsia, increased appetite, sedation, and somnolence. 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 the VA Maryland Health Care System, 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:

Litten RZ, Fertig JB, Falk DE, Ryan ML, Mattson ME, Collins JF, Murtaugh C, Ciraulo D, Green AI, Johnson B, Pettinati H, Swift R, Afshar M, Brunette MF, Tiouririne NA, Kampman K, Stout R; NCIG 001 Study Group. A double-blind, placebo-controlled trial to assess the efficacy of quetiapine fumarate XR in very heavy-drinking alcohol-dependent patients. Alcohol Clin Exp Res. 2012 Mar;36(3):406-16. doi: 10.1111/j.1530-0277.2011.01649.x. Epub 2011 Sep 26. PMID: 21950727; PMCID: 21950727

Data Access Application Procedure and Access Policy

The NCIG 001 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 001 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 001 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 001

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 001 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 001 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