NIAAA Data Access Application

NCIG 003 - A Phase II, Double-Blind, Placebo Controlled Trial to Assess the Efficacy of Varenicline Tartrate for Alcohol Dependence

Title of Research Project:

Introduction

This double-blind, randomized placebo-controlled trial evaluated the efficacy and safety of varenicline tartrate, recruiting 200 alcohol-dependent patients from 5 sites. All subjects received either varenicline tartrate or placebo and the Take Control computerized behavioral platform. Patients were stratified on clinical site and regular smoking (10+ cigarettes smoked per day). Across the study maintenance phase (weeks 2-13), the varenicline group had significantly lower weekly percent heavy drinking days (primary outcome) (adjusted mean difference = 10.4), drinks per day, drinks per drinking day, percent very heavy drinking days, alcohol craving, and cigarettes smoker per day, compared with the placebo group ($P < 0.05$). Varenicline was well-tolerated; adverse events were expected and mild. Three adverse events occurred at statistically greater rates in the varenicline group that the placebo group: nausea (37.1% vs 17.8%, respectively); abnormal dreams (27.8% vs 11.9%, respectively); and constipation (9.3% vs 2.0%, respectively). 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:

Litten RZ, Ryan ML, Fertig JB, Falk DE, Johnson B, Dunn KE, Green AI, Pettinati HM, Ciraulo DA, Sarid-Segal O, Kampman K, Brunette MF, Strain EC, Tiouririne NA, Ransom J, Scott C, Stout R; NCIG (National Institute on Alcohol Abuse and Alcoholism Clinical Investigations Group) Study Group. A double-blind, placebo-controlled trial assessing the efficacy of varenicline tartrate for alcohol dependence. J Addict Med. 2013 Jul-Aug;7(4):277-86. doi: 10.1097/ADM.0b013e31829623f4. PMID: 23728065; PMCID: PMC3914416.

Data Access Application Procedure and Access Policy

The NCIG 003 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 003 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 003 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 003

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 003 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 003 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