

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 than 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. 2013. A double-blind, placebo-controlled trial assessing the efficacy of varenicline tartrate for alcohol dependence. *J Addict Med* 7(4):277-86.

Data Access Application Procedure and Access Policy

The NCIG 003 data set contains individual level data, as such, it is categorized as a controlled access data set. Access will only be granted to research investigators who, along with their institutions, have certified their agreement with the expectations and terms of the access detailed in this document.

Qualified researchers should: (1) complete the Data Access Application form below, (2) provide a fully executed the Data Use Agreement, and (3) provide a copy of the IRB letter of exemption or approval. This agreement is designed to protect the integrity of the data set and assure client confidentiality. Note that the signature and concurrence of your authorized institutional official is also required. This is ordinarily someone from your technology transfer office. Completed applications may be submitted by email to:

NIAAA-DAC@mail.nih.gov

(application starts next page)

NCIG 003 - Varenicline for Alcohol Dependence
Data Access Application

Title of Research Project: _____

Date of Application: _____

New

Renewal

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 # _____

List collaborators and data analysts (including students), if different from applicant. Collaborators and data analysts are herein defined as those individuals who will have direct access to the requested database; individuals who may contribute to scientific papers and other works, but do not have direct access, are not considered collaborators for the purpose of this data access application.

If applicant is a student who wishes to use this data set in a thesis or dissertation, a faculty sponsor must submit this application and self-identify as the Applicant/P.I. Information regarding the student should be provided below.

Collaborators, Analysts, Students and other Users

Name:

Title:

Affiliation:

Address:

Telephone:

Email:

Degree(s) Held:

Major Discipline/Field of Study:

Name:

Title:

Affiliation:

Address:

Telephone:

Email:

Degree(s) Held:

Major Discipline/Field of Study:

Name:

Title:

Affiliation:

Address:

Telephone:

Email:

Degree(s) Held:

Major Discipline/Field of Study:

Name:

Title:

Affiliation:

Address:

Telephone:

Email:

Degree(s) Held:

Major Discipline/Field of Study:

Please add additional individuals, as necessary, in a separate Word document and provide it with this application to NIAAA.

Exhibit A

Research Project Description

Please briefly describe your research plan in the space below.

Exhibit A

Research Project Description

Continued - Extra Space