

DSMB Charter

Evaluation of Medical Cannabis and Prescription Opioid Taper Support for Reduction of Pain and Opioid Dose in Patients with Chronic Non-Cancer Pain
2021P000871

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NIDA R01 DA051540-01A1

A. Safety monitoring

An independent Data and Safety Monitoring Board (DSMB) will be appointed for this study, to assess the safety of the study by determining whether there is an unacceptable level of risk due to study procedures and whether an increased number of adverse events occur.

The DSMB will be established to analyze interim results to assess the safety of the trial at regular intervals for the duration of the study by determining whether an increased number of adverse events occur among study participants receiving drug compared to participants receiving placebo.

The board will include a statistician, an addiction expert, and a psychiatrist. Each member of the DSMB will not otherwise be associated with the trial. Safety data will be reviewed by the Data and Safety Monitoring Board every 6 months after the recruitment period begins. The DSMB will receive summary reports on recruitment, retention and description of all adverse events and review them at each biannual DSMB meeting. The DSMB will receive all communication with the IRB. Subject information provided to the board will be identified only with study IDs to protect the confidentiality of subjects. The DSMB will assess interim results to determine whether the active drug treatment is associated with substantial risk, including higher rate of adverse outcomes when compared with the placebo group.

B. Outcomes monitoring

A DSMB Report written by the chair and approved by all members will be issued to the IRB after every DSMB meeting. The report will include, but may not be limited to, a synopsis of the trials, their progress to date, characteristics of participants enrolled, retention and disposition of study participants, quality assurance issues, regulatory issues, and reports of AEs and SAEs.

DSMB Role	Name and title	Affiliation / Institution	Contact details	Summary of expertise
DSMB Chair and Medical Safety Officer	David Mischoulon, MD	MGH	dmischoulon@mgh.harvard.edu	depression, complementary and alternative medicine
DSMB Biostatistician	Susanne Hoepfner, PhD	Harvard Medical School	shoepfner@mgh.harvard.edu	biostatistician and epidemiologist
DSMB Addiction Expert	Amy Janes, PhD	Harvard Medical School	ajanes@mclean.harvard.edu	neuroimaging, brain function, drug use and relapse.

Trial investigators will not be members of the DSMB.