ALCOHOL AND SUBSTANCE USE DISORDERS RESEARCH PROGRAM



Vision: Improve the clinical outcomes of alcohol, opioid, and other substance use disorders

Mission: To identify, evaluate and advance pharmacotherapeutics for alcohol, opioid and other substance use disorders, with an emphasis on other co-occurring mental health conditions, to maximize the functioning and quality of life for Service Members, their Families, Veterans, and the American public

FY24 Appropriation \$4M

PROGRAM DESCRIPTION

Congress first appropriated funds in 2010 to create the Alcohol and Substance Use Disorders Research Program to address the problem of alcohol and other substance use disorders among Service Members, Veterans, and the general public. In FY21, Congress prioritized research on substance use disorders aimed at reducing the overall number of opioid-related overdose deaths due to the ongoing threat to Warfighters and the general public. The ASUDRP established a network of multidisciplinary, translational research teams with the explicit goal of accelerating the delivery of new or improved treatments for ASUD.

PROGRAM OBJECTIVES

- To increase and improve medication options for treating alcohol and other substance use disorders, particularly when co-occurring with PTSD, TBI, and/or other mental health conditions
- To reduce the number of opioid and other substance use-related deaths



ANTICIPATED FY24 FUNDING MECHANISM

The ASUDRP is offering the Consortium Award mechanism. The population of interest includes individuals with alcohol and other substance use disorders, including opioid use disorder, particularly when co-occurring with PTSD, TBI, and/or other mental health conditions.

CONSORTIUM AWARD

Investigators at all academic levels or equivalent

- Supports a single operations center to solicit and provide oversight and management of basic research and clinical trials within the consortium.
- Principal investigator will provide leadership to facilitate collaboration of multiple organizations and individuals with the goal of translating basic science knowledge into evidence-based treatments for alcohol and other substance use disorders.
- PI with strong, collaborative leadership experience will manage a consortium of highly qualified, multidisciplinary subject matter experts.
- The consortium management core is encouraged to include individual(s) with lived experience as consultant(s) to the leadership team.
- Submission of a Letter of Intent is required prior to full application submission.

\$3.525M for total costs, including direct and indirect costs

Two option periods, FY25–FY26, pending future appropriations totaling up to **\$4M** each.

Maximum period of performance is **5 years**.



For more information visit https://cdmrp.health.mil/asudrp



GOAL 1: Identify



Identify new chemical entities and repurpose existing medications in preclinical and non-clinical research models, including Investigational New Drug Application-enabling studies, for the treatment of ASUD with co-occurring PTSD and other mental health conditions.

GOAL 2: Evaluate

Strategic Goals



Evaluate candidate medications, including assessment of safety, pharmacokinetics and pharmacodynamics, to determine optimal dosing in individuals with ASUD, or ASUD with co-occurring PTSD and other mental health conditions, or healthy volunteers, as needed.

GOAL 3: Advance



Advance potential treatments by testing the preliminary efficacy and safety of medications or medication combinations in individuals with ASUD, or ASUD with co-occurring PTSD and other mental health conditions; as well as explore precision medicine tools for improved treatment outcomes for individual patients.

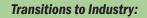
Focus Areas

To treat ASUDs, particularly when co-occurring with PTSD, TBI, and/or other mental health conditions:

- New medication targets
- Novel medications
- Re-purposed medications

- Vaccines and other immunotherapies
- Drug-drug combinations
- More potent, longer-acting formulations to counteract opioid (including fentanyl and its analogs) overdose

Driving Impact



- Preclinical data supported further development of ASP8062 → Astellas pursuing ASP8062 as a potential treatment for AUD. ASP8062 is a GABAb receptor positive allosteric modulator
- Preclinical data suggested CERC-501 may be useful in treating PTSD → Janssen Pharmaceuticals procured rights to CERC-501 from Cerecor for further development as a treatment for major depressive disorder. CERC-501 is a kappa opioid receptor antagonist



- Preclinical data demonstrated efficacy of the anti-fentanyl vaccine alone and in combination with buprenorphine

 Supports future clinical development of the vaccine for OUD in combination with current FDA approved treatments
- Provisional patent application submitted



"ASUDRP is a pivotal program, uniting experts to confront the problem of alcohol and substance use disorders intertwined with PTSD, impacting military personnel and Veterans.... With every grant awarded, ASUDRP propels us closer to combating addiction and trauma more effectively, curbing the opioid crisis, and enhancing lives."

Jana Drgonova, Ph.D., National Institutes of Health, National Institute on Drug Abuse,
ASUDRP Programmatic Panel Member, FY19-FY22

