## **Call for Pilot Studies Preparatory to Large Clinical Trials:**

## Complementary and Integrative Health Interventions to Support Deprescribing of Benzodiazepine Receptor Agonists in Older Adults

Benzodiazepine receptor agonists, which include classic benzodiazepines as well as the "Z-drugs" such as zolpidem, are a major source of problematic prescribing for older adults and confer substantial harms. Approaches using complementary and integrative health approaches to support deprescribing these medications show promise, yet studies in this area are for the most part small and of limited methodologic quality. There is a need for high-quality controlled clinical trials of complementary and integrative health (CIH) approaches to determine their effectiveness for helping older adults reduce use of these medications.

The US Deprescribing Research Network (USDeN) has applied for a directed funding opportunity from the National Center for Complementary and Integrative Health (see <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-AT-22-012.html">https://grants.nih.gov/grants/guide/notice-files/NOT-AT-22-012.html</a>) to solicit, select, and fund large pilot studies in this topic area that can, upon completion, lead directly to large and definitive clinical trials. While USDeN's application has not yet been approved, it is highly likely that it will be funded, with a likely start date in August 2022. After this date, there will be a short timeline for research groups to apply for pilot funds through this mechanism. We thus strongly encourage people who may be interested in applying for pilot funds to begin developing their ideas and research team during this spring and early summer.

We anticipate funding approximately 4 one-year pilot studies, each with a budget of up to approximately \$160,000 (combined directs and indirects). These studies should pilot test interventions that use complementary and integrative health modalities to support deprescribing of benzodiazepine receptor agonists (i.e. benzodiazepines and/or "Z drugs") in older adults. The goal of these studies should be to test study procedures, refine the intervention, assess feasibility and acceptability, and/or other such goals, such that by the end of the one-year study period the research team will be well-positioned to apply for a large grant funding opportunity to conduct a definitive clinical trial. The scope of what constitutes a complementary and integrative health intervention is not tightly defined, but may include psychologically based interventions such as cognitive behavioral therapy or relaxation techniques, somatic therapies such as massage, and/or pharmacologic interventions such as herbal supplements. While all CIH modalities will be considered, strong justification for pharmacologic substitutes will be required, given potential for adverse effects in older adults and their contribution to excessive polypharmacy. Interventions which, if proven effective, have potential for future widespread dissemination are especially encouraged. We strongly encourage inclusion of diverse populations of older adults and require attention to NIH's guidance regarding inclusion across the lifespan, and all applications will be required to have a stakeholder engagement plan (for additional information, see https://deprescribingresearch.org/network-activities/engaging-stakeholders-in-research/).

The anticipated timeline for this opportunity is as follows: <u>August 2022</u> – release of official Request for Applications for the pilot award program; <u>Early fall 2022</u> – informational webinar and due date for letters of intent; <u>Mid-fall 2022</u>: applications due; <u>Late fall / early winter 2022</u> – applications selected and funded; projects begin.

Applications will be reviewed by a study section convened by USDeN that includes both scientific and stakeholder reviewers. This award mechanism will be administered using USDeN's existing pilot award infrastructure. While this special opportunity is distinct from the main series of pilot and grant planning awards that USDeN funds annually, we encourage applicants to familiarize themselves with that legacy program (<a href="https://deprescribingresearch.org/network-activities/grant-opportunities/">https://deprescribingresearch.org/network-activities/grant-opportunities/</a>), since many of the processes for reviewing applications and supporting investigators will be similar.

We strongly encourage investigators who might be interested in applying – or simply learning more – to contact the US Deprescribing Research Network at <a href="mailto:admin@deprescribingresearch.org">admin@deprescribingresearch.org</a>. We are happy to answer questions, and once we know who you are we will be able to provide updates about this funding opportunity as they become available.