

Repurposing Research to Improve Patient Outcomes in Meniere's Disease and Related Diagnoses: Clinical and Preclinical Projects



OVERVIEW

This Request for Proposals (RFP) from [Cures Within Reach](#) (CWR) is seeking both clinical repurposing trials and preclinical repurposing projects to address Meniere's disease (MD) as well as other vertigo and hearing loss-related diagnoses, such as benign paroxysmal positional vertigo (BPPV), tinnitus, labyrinthitis and vestibular neuritis, to improve patient outcomes. **Repurposed therapies must be approved and/or generally recognized as safe for human use by some regulatory agency**, such as the US Food and Drug Administration, European Medicines Agency, Health Canada or Japan's Pharmaceuticals and Medical Devices Agency, and can include **drugs, devices, nutraceuticals, other eligible treatments/therapies or combination therapies**.

CWR is accepting budgets of up to \$100,000 for clinical trials and budgets up to \$50,000 for preclinical projects for this RFP, which includes the required 20% institutional match (see Important Funding Information below). Submissions may come from accredited academic, nonprofit and governmental research institutions and/or health systems significantly involved with medical research located anywhere in the world.

CWR has a 2-stage submission process, starting with a Letter of Intent (LOI). All submissions for this RFP are via our online grant management platform on ProposalCentral at <https://bit.ly/submittocwr> using the **Disease Specific Repurposing Research** program. For LOI submission instructions and more information about CWR's funding opportunities, visit <https://bit.ly/cwrrfps>.

LOIs for this RFP will be reviewed, scored and ranked by CWR staff, our external Grant Review Committee and/or our Science Advisory Board (SAB) members, and the top-rated LOI submissions will be invited to submit a full proposal as the second stage. Principal Investigators (PIs) will be contacted approximately 6-8 weeks following the LOI submission deadline with a decision.

The LOI submission deadline is 11:59pm U.S. Central Time on March 20, 2023. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions.

FULL DESCRIPTION

Background

This RFP from CWR is seeking both clinical repurposing trials and preclinical repurposing projects to address Meniere's disease (MD) as well as other vertigo and hearing loss-related diagnoses, such as benign paroxysmal positional vertigo (BPPV), tinnitus, labyrinthitis and vestibular neuritis. We are interested in generic or proprietary drugs, devices, nutraceuticals or other eligible therapies that could be repurposed to create "new" treatments to 1) reduce the symptoms, progression or incidence of; 2) restore function lost to; or 3) to reduce or eliminate severe side effects of currently used therapies for MD and/or other vertigo and hearing loss-related diagnoses, thereby improving patient outcomes and quality of life.

Repurposed therapies can include drugs, devices, nutraceuticals, other eligible treatments/therapies or some combination of therapies. Repurposed therapies must be approved and/or generally recognized as safe for human use by some regulatory agency, such as the US Food and Drug Administration, European Medicines Agency, Health Canada or Japan's Pharmaceuticals and Medical Devices Agency. Repurposed therapies can be used alone or in combination with other therapies, including the current standard of care.

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Cures Within Reach is circulating this RFP because MD and/or other vertigo and hearing loss-related diagnoses are currently partially or fully unsolved. An unsolved disease is one in which one or more of the following are true:

- There is currently no effective treatment
- The current treatment is only effective for a portion of the patient population
- There is a treatment that is effective, but many patients develop resistance to the therapy
- There is a treatment that is effective for the entire patient population, but the treatment is very expensive, and therefore some patients cannot get access to the treatment
- There is a treatment that is effective for the entire patient population with significant side effects, and for some patients the negative side effects outweigh the benefits of the treatment

If you have a repurposing idea in MD and/or other vertigo and hearing loss-related diagnoses that isn't an exact fit for this RFP, or **if you have eligibility questions due to budget or other aspects, please contact Clare Thibodeaux, PhD at clare@cureswithinreach.org to discuss fit and/or submission options.**

Many of our successes in repurposing have come from researchers and clinicians who had ideas that could impact a disease that was outside their normal therapeutic or scientific area. Please submit your repurposing ideas, find colleagues to work with and circulate this RFP to others who you think might be able to submit repurposing research that could provide solutions for an unsolved disease.

Eligible submissions may:

- Repurpose approved and/or generally recognized as safe drugs, devices, nutraceuticals or other eligible treatments/therapies
- Test combination therapies to increase their efficacy, including combining the current disease treatment with a repurposed treatment or combining multiple repurposed therapies
- Repurpose therapies approved for use in adults into pediatric indications, or vice versa
- Come from accredited academic, nonprofit and governmental research institutions and/or health systems significantly involved with medical research located anywhere in the world, where good scientific research and clinical practices can be assured
 - Although start-ups, biotechs, pharmaceutical companies and medical device companies are not eligible for this RFP, their collaborators at eligible institutions can apply. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org for more information.
- Be led either by a previously funded investigator or by an early-stage investigator who has received little or no extramural research funding to date
 - PIs who have not received extramural funding previously and/or who do not currently have their own lab should include a Letter of Support from a funded, senior researcher who will act as a mentor for the proposed research and the investigator
- Not yet have funding (see Important Funding Information below) or already have funding from another source, when funding from CWR will help improve the chances of success of the project and/or help speed patient impact

Preferred submissions include:

- Clinical: Our strongest preference is for proof of concept repurposing clinical research trials supported by strong preclinical evidence or clinical observations. We may also consider later stage clinical trials that require additional funding.

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- CWR is open to all clinical trial designs (open label, cross-over, dose determination, randomized, blinded, controlled, etc.) that have the opportunity to create a robust and well-defined outcome that will show reproducible clinical impact and/or generate data that can be leveraged into follow-on funding from other sources and additional clinical trials.
- **Preclinical:** Our strongest preference is for late-stage preclinical repurposing research projects that are the last step(s) before moving into patients. We will also consider other types of earlier stage preclinical repurposing research that have a translational focus, including drug screening, bioinformatics, genotyping or 'omics studies, cell-based assays and animal models.
 - Preclinical projects should follow an experimental design and plan that allows for appropriate statistical analyses and reproducibility of the data, resulting in data that can be leveraged into follow-on funding from other sources and additional studies.
 - Preclinical LOI submissions would be strengthened by 1) ideas of how positive results may be used in a clinical setting to create patient impact, and/or 2) a supporting letter from a clinical collaborator willing to begin clinical trials once positive results are seen.

Important Funding Information

CWR is accepting budgets of up to \$100,000 for clinical trials and budgets up to \$50,000 for preclinical projects for this RFP, which includes the required 20% institutional match. **CWR will provide no more than 80% of the total funding amount submitted to CWR, and the PI's research institution will match at least 20% of the total funding amount submitted to CWR.** All funding requests are in US dollars.

For example, if the total funding amount submitted to CWR is \$100,000, CWR will provide 80% or \$80,000 and the research institution will provide 20% or \$20,000. Submitting an LOI does not commit the PI or the research institution to the 20% institutional match. If a submission is selected to move beyond the LOI stage, we will contact the PI and the research institution about this requirement.

The 20% institutional match must be real dollars committed to the project and can include indirect costs. The institutional match may come from the research institution itself (including salaries, patient costs, etc.); from government or other public funders; from individuals, foundations or other private funders; from industry (including the dollar value of donated drug); or from any combination of these sources. The CWR portion of the requested total funding amount cannot be used for indirect costs. However, **the 20% institutional match may be used for indirect costs.**

The total funding amount submitted to CWR must be sole, late or final funding required to accomplish the specific aims listed in the LOI. CWR funding cannot be the first funding raised for a project unless it is also the sole funding needed. The 20% institutional match is not counted as additional funds to be raised. Below are some general examples to help explain:

- The project will cost \$100,000 to complete, and the maximum funding amount of the RFP is \$100,000. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$200,000 in existing funding / support. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$0 in existing funding / support. This project is not eligible for funding from CWR.

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If you have eligibility questions due to the budget or funding amount for your project, please contact Clare Thibodeaux, PhD at clare@cureswithinreach.org.

CWR is open to working with other funders who share our desire to address MD and/or other vertigo and hearing loss-related diagnoses and are interested in these near-term repurposing opportunities. **We will accept projects that already have funding from another source, when this additional funding from CWR will help improve the chances of success of the project, and therefore increase the chance of patient impact.**

Submitting Your LOI and Due Date

All submissions for this RFP are via CWR's online grant management platform on ProposalCentral at <https://bit.ly/submittocwr> using the **Disease Specific Repurposing Research** program. If you're already a ProposalCentral user, log into your existing account to submit. If you don't already have a ProposalCentral account, create a login at <https://proposalcentral.com/>.

The LOI submission deadline is 11:59pm U.S. Central Time on March 20, 2023. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions / issues about the LOI submission deadline.

For LOI submission instructions and more information about all of CWR's funding opportunities, visit <https://bit.ly/cwrrfps>.

Review Criteria and Review Process

Repurposing innovation, feasibility of the research plan, relevance to the patient population, potential clinical impact, "value" of the research for the funding and the research team are key ranking criteria for a successful LOI submission. LOIs for this RFP will be reviewed, scored and ranked by CWR staff, our external Grant Review Committee and/or our Science Advisory Board (SAB) members, and the top-rated LOI submissions will be invited to submit a full proposal. PIs will be contacted approximately 6-8 weeks following the LOI submission deadline with a decision.