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

CUREACCELERATOR®
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CuresWithinReach

OVERVIEW

This Request for Proposals (RFP) from Cures Within Reach (CWR) is seeking collaborative, multisite clinical repurposing trials to address Meniere's disease, as well as other related vertigo and hearing loss-related diagnoses, such as benign paroxysmal positional vertigo (BPPV), tinnitus, labyrinthitis and vestibular neuritis, to improve patient outcomes and quality of life. CWR may also accept translational preclinical repurposing studies that are designed to advance repurposed therapies to clinical trials or combination preclinical/clinical studies that together produce robust data for publications, presentations, follow on funding and potential off label use of repurposed therapies. Submissions can come from accredited academic, nonprofit and governmental research institutions and/or health systems significantly involved with medical research **located anywhere in the world**.

CWR is interested in generic or proprietary approved therapies that could be repurposed to create "new" treatments that 1) reduce the symptoms, progression or incidence of; 2) restore function lost to; or 3) reduce or eliminate severe side effects from current therapies for Meniere's disease and other vertigo and hearing-loss diagnoses.

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 or combination therapies**. These repurposed therapies must be tested in a new indication for which they are not already approved or used widely in clinical practice as standard of care. Repurposed therapies may be added to current standard of care to improve patient outcomes and/or quality of life.

CWR is accepting budgets of up to $350,000 for collaborative, multisite clinical trials. CWR may also accept budgets up to $100,000 for translational preclinical studies for this RFP. Submitted budgets must include the required institutional match (see Important Funding Information below). If you have an idea for a preclinical or combination preclinical/clinic study, please contact CWR directly before submitting to discuss fit and/or submission options.

Clinical trial designs should take into account the high placebo effect found in Meniere's disease research, and all studies should have an experimental design and plan that allows for appropriate statistical analyses and reproducibility of the data.

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 (https://www.proposalcentral.com). If you're already a ProposalCentral user, log in to your existing account to submit. If you don't already have a ProposalCentral account, create a login. Next, navigate to the "Grant Opportunities" tab and search for "Cures Within Reach." Submit your proposal using the **Disease Specific Repurposing Research** program. Click on the "Apply Now" button on the right to begin a submission. For 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 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. Eastern Time on June 13, 2025. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions.

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FULL DESCRIPTION

Background

This RFP from CWR is seeking collaborative, multisite clinical repurposing trials to address Meniere's disease, as well as other related vertigo and hearing loss-related diagnoses, such as benign paroxysmal positional vertigo (BPPV), tinnitus, labyrinthitis and vestibular neuritis, to improve patient outcomes and quality of life. CWR may also accept translational preclinical repurposing studies that are designed to advance repurposed therapies to clinical trials or combination preclinical/clinical studies that together produce robust data for publications, presentations, follow on funding and potential off label use of repurposed therapies.

We are interested in generic or proprietary drugs, devices, nutraceuticals or other eligible therapies that could be repurposed to create "new" treatments that 1) reduce the symptoms, progression or incidence of; 2) restore function lost to; or 3) to reduce or eliminate severe side effects from current therapies for Meniere's disease and/or other vertigo and hearing loss-related diagnoses, thereby improving patient outcomes and quality of life.

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 or combination therapies**. These repurposed therapies must be tested in a new indication for which they are not already approved or used widely in clinical practice as standard of care. Repurposed therapies may be added to current standard of care to improve patient outcomes and/or quality of life.

If you have a repurposing idea in Meniere's disease and/or other vertigo and hearing loss-related diagnoses that isn't an exact fit for this RFP, or **if you have an idea for a single site clinical repurposing trial, a preclinical trial or a combination preclinical/clinical trial, 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 must:

- Be in Meniere's disease or other vertigo and hearing loss-related diagnoses such as benign paroxysmal positional vertigo (BPPV), tinnitus, labyrinthitis and vestibular neuritis, and repurpose approved and/or generally recognized as safe drugs, devices or nutraceuticals, either alone or in combination
    - Repurposed therapies can also be added to current standard of care therapies
- Be collaborative, multisite, interventional clinical trials
    - **Clinical trial designs should take into account the high prevalence of the placebo effect** in Meniere's disease and related conditions and should use a conservative estimate in the power analysis when determining the sample size needed for statistically significant results
    - If you have an idea for a single site interventional clinical trial, please contact CWR for submission options
- Have a timeline of no longer than 48 months for clinical trials or 36 months for preclinical studies
- Be conducted at an accredited academic, nonprofit or governmental research institution and/or health system 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
- 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

Although CWR has a preference for collaborative, multisite clinical trials, we may consider 1) strong, translational preclinical projects that are designed to advance repurposed therapies to clinical trials and that utilize human cell/tissue based systems or 2) combination preclinical/clinical studies that together produce robust data for publications, presentations, follow on funding and potential off label use of repurposed therapies. **If you have an idea for a preclinical or combination preclinical/clinic study, please contact CWR directly before submitting to discuss fit and/or submission options.**

Preferred submissions include:

- Clinical: Our strongest preference is for collaborative, multisite, Phase I/Phase IIA clinical repurposing trials supported by preclinical evidence, real world evidence, AI/ML drug-disease matching tools and/or clinical observations. We may also consider larger multisite Phase IIB/Phase III clinical trials that require additional funding or single site clinical trials in certain situations. **Please contact CWR directly to discuss fit/submission options of any single site clinical trials.**
    - 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, additional clinical trials and /or potential off-label use of repurposed therapies.
- Preclinical: Preclinical repurposing research studies using human cell/tissue models are preferred over animal models. Preclinical studies based on data or hypotheses generated through AI/machine learning technologies are also preferred.
    - Preclinical studies 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 pilot clinical studies.
    - **Preclinical studies should have a translational focus** and 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.
    - **Please contact CWR directly to discuss fit/submission options of any preclinical repurposing studies.**
- CWR may also accept preclinical/clinical combination submissions, when the studies are complementary and together produce robust data for publications, presentations, follow on funding and potential off label use. **Please contact CWR directly to discuss fit/submission options of combination preclinical/clinical studies.**

Important Funding Information

CWR is accepting budgets of up to $350,000 for collaborative, multisite clinical trials. CWR may also accept budgets up to $100,000 for translational preclinical studies for this RFP. Submitted budget must include the required institutional match. If you have an idea for a combination preclinical/clinic study, please contact CWR directly about the budget.

The PI's research institution will provide matching funding based on the total funding amount submitted to CWR (see table below), and CWR will provide no more than the remaining balance of the total funding amount submitted to CWR. All funding requests are in US dollars.

Total Funding Amount Submitted to CWR	Required Institutional Match
$200,000 or lower	20% of the total budget submitted
$200,001 and above	15% of the total budget submitted

For example, if the total funding amount submitted to CWR is $350,000, CWR will provide 85%, or $297,500, and the research institution will provide 15%, or $52,500. If the total funding amount submitted to CWR is $180,000, CWR will provide 80%, or $144,000, and the research institution will provide 20%, or $36,000. Submitting an LOI does not commit the PI or the research institution to the 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 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.

CWR allows for up to 20% of the total funding amount submitted to be used for indirect costs. Any amount of the institutional match may be used for indirect costs. **For budgets of $200,000 or less, CWR funds may not be used for indirect costs. For budgets of more than $200,000, up to 5% of CWR funds 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 institutional match is not counted as additional funds to be raised. Below are some general examples to help explain:

- The project will cost $350,000 to complete, and the maximum funding amount of the RFP is $350,000. This project is eligible for funding from CWR.
- The project will cost $750,000 to complete, and the maximum funding amount of the RFP is $350,000. The PI has already secured $400,000 in existing funding / support. This project is eligible for funding from CWR.
- The project will cost $750,000 to complete, and the maximum funding amount of the RFP is $350,000. The PI has already secured $0 in existing funding / support. This project is not eligible for funding from CWR.

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 Meniere's disease 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 our online grant management platform on ProposalCentral (https://www.proposalcentral.com). If you're already a ProposalCentral user, log in to your existing account to submit. If you don't already have a ProposalCentral account, create a login. Next, navigate to the "Grant Opportunities" tab and search for "Cures Within Reach." Submit your proposal using the **Disease Specific Repurposing Research** program. Click on the "Apply Now" button on the right to begin a submission.

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Review Criteria and Review Process

Repurposing innovation, feasibility of the research plan, relevance to the patient population, potential clinical impact 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 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.