Repurposing Research to Improve Clinical Patient Outcomes in Meniere's Disease and Related Symptoms / Consequences

Description / Background
This Request for Proposals is seeking clinical repurposing trials to address address Meniere’s disease (MD) and symptoms/consequences of MD, including tinnitus and hearing loss with up to $100,000 available in total funding. We are interested in generic or proprietary drugs, devices, nutraceuticals or diagnostics 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 related symptoms/consequences, including tinnitus and hearing loss, thereby improving patient outcomes and quality of life.

Repurposed therapies can be used alone or in combination with other therapies. Repurposed therapies must be approved and/or 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.

Additional Proposal submission instructions can be downloaded at this link: https://bit.ly/cwrclinicalrfp.

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 if our additional funding will help speed the patient impact of the clinical trial.

If you have a repurposing idea in MD and/or related symptoms/consequences, including tinnitus and hearing loss 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.

No preclinical research projects, including animal studies, will be accepted for this RFP. However, Cures Within Reach has up to $50,000 in funding available for preclinical repurposing research in MD and/or related symptoms/consequences, including tinnitus and hearing loss in a separate RFP. PIs are welcome to apply to both RFPs, for either independent or combination projects. To see the details of the preclinical RFP, click this link: https://app.cureaccelerator.org/rfp/view/109.
Cures Within Reach is circulating this RFP because MD and/or related symptoms/consequences, including tinnitus and hearing loss 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

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.

Important Funding Information:

Cures Within Reach will provide no more than 80% of the REQUESTED PROJECT FUNDING, and the institution, organization or company proposing the research will match at least 20% of the REQUESTED PROJECT FUNDING. The REQUESTED PROJECT FUNDING is equal to the ESTIMATED OVERALL PROJECT COSTS in the BUDGET BREAKDOWN section of the proposal submission, and includes the 20% Institutional Match.

The Institutional Match must be real dollars committed to the project, not in-kind efforts, and can include Indirect Costs. The Institutional Match can come from the Research Institution itself (including salaries, patient costs, etc.); from government or other public funders; from individuals, foundations or other private funders; or from any combination of these sources.

All funding requests are in US dollars.

Funding Definitions:

- Project Funding = total research budget (no set maximum)
- Remaining Project Funding = funding needed to reach the total research budget (no set maximum)
- Existing Project Funding = Project Funding minus Remaining Project Funding (no set maximum)
- Requested Project Funding = funding requested through this RFP (maximum = $100,000, including the 20% institutional match)
- Budget Breakdown = breakdown of the Requested Project Funding (maximum total = $100,000, including 20% institutional match)
- Estimated Overall Project Costs = Requested Project Funding (see above)

Cures Within Reach will accept REQUESTED PROJECT FUNDING amounts that are within the minimum and maximum amounts indicated. We do not set an upper limit to the PROJECT FUNDING, or the EXISTING PROJECT FUNDING, but REQUESTED PROJECT FUNDING amounts to Cures Within Reach are limited to the maximum amount specified in the Funding
Information section below. Proposals may be submitted for which the PROJECT FUNDING is within the Cures Within Reach maximum, and for projects that already have EXISTING PROJECT FUNDING from another source and require REMAINING PROJECT FUNDING, when this additional funding from Cures Within Reach will help speed patient impact.

Cures Within Reach REQUESTED PROJECT FUNDING must be sole, late or final funding for the project. REQUESTED PROJECT FUNDING from Cures Within Reach cannot be the first funding raised for a project, unless the REQUESTED PROJECT FUNDING, including the 20% Institutional Match, equals the PROJECT FUNDING.

Here are two examples of funding requests and disbursements to help investigators and institutions understand the funding opportunity.

Example A
The maximum funding request to CWR is $100,000. The PI enters $100,000 for REQUESTED PROJECT FUNDING and for ESTIMATED OVERALL PROJECT COSTS in the BUDGET BREAKDOWN, which equals the PROJECT FUNDING. CWR approves this project, and will provide $80,000 (80% of the REQUESTED PROJECT FUNDING) and the investigator/institution will match the remaining $20,000 of the REQUESTED PROJECT FUNDING.

Example B
The maximum funding request to CWR is $100,000. The PI enters $100,000 for REQUESTED PROJECT FUNDING and for ESTIMATED OVERALL PROJECT COSTS in the BUDGET BREAKDOWN, which will cover one-third of the $300,000 entered for PROJECT FUNDING. The other $200,000 is entered for EXISTING PROJECT FUNDING, and has already been secured by the investigator and institution. CWR approves this project, and will provide $80,000 (80% of the REQUESTED PROJECT FUNDING) and the investigator/institution will match the remaining $20,000 of the REQUESTED PROJECT FUNDING and provide the $200,000 of the EXISTING PROJECT FUNDING.

Cures Within Reach REQUESTED PROJECT FUNDING cannot be used for any Indirect Costs, although the 20% Institutional Match may be used for Indirect Costs.

Diseases/Conditions

- Meniere's disease
- Tinnitus
- Hearing Loss

Treatments

- Any repurposed drug, device, nutraceutical or diagnostic

Project Type

- Human Clinical Trial

Timeline
Do you have a preference for where the research should take place?
This research can take place anywhere in the world where good scientific research and clinical practices can be assured. This RFP is open to accredited academic, nonprofit and governmental research institutions and large group medical practices significantly involved with medical research. Start-ups, biotechs, pharmaceutical companies and medical device companies may also be eligible to apply. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org to learn more about eligibility for companies.

Do you have a preference for where you would like to see patient impact?
Our main focus is on repurposing research in Meniere's disease and/or related symptoms/consequences, including tinnitus and hearing loss. We are hopeful that any discovery would be useful anywhere in the world where the repurposed therapy is available.

Restrictions
There are no other restrictions other than those described above.

Other Information for Researchers
Cures Within Reach and our funders primarily fund proof of concept clinical trials that can determine whether a repurposed therapy can have a direct and positive impact on patients. Sometimes the clinical trials in our portfolio are open label studies with clinical endpoints that compare to the natural history of the disease. Some clinical trials are dose determination studies. Other clinical trials are randomized, blinded and controlled studies. We are open to all clinical trial designs that have the opportunity to create a robust and well-defined outcome that will show reproducible clinical impact and that can be leveraged into follow-on funding from other sources and additional clinical research.

Cost effectiveness, speed and patient impact are key ranking criteria for a successful Proposal submission. Cures Within Reach expects to select a small number of Proposals for a Full Grant submission. PIs will receive a decision on their Proposal within approximately 6-8 weeks of the RFP deadline.

Funding Available
Minimum $25,000

Maximum $100,000

Funding Description
See full Funding information in the Research Description section above. Cures Within Reach will
accept REQUESTED PROJECT FUNDING amounts that are within the minimum and maximum amounts indicated. Cures Within Reach REQUESTED PROJECT FUNDING must be sole, late or final funding for the project, as indicated in the Research Description. Cures Within Reach will provide no more than 80% of the REQUESTED PROJECT FUNDING, and the institution, organization or company proposing the research will match at least 20% of the REQUESTED PROJECT FUNDING. The Institutional Match must be real dollars committed to the project, not in-kind efforts, and can include Indirect Costs. The Institutional Match can come from the Research Institution itself (including salaries, patient costs, etc.); from government or other public funders; from individuals, foundations or other private funders; or from any combination of these sources. All funding amounts are in US dollars.

Open to co-funding

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**Co-Funding Description**

Open to co-funding. We will accept projects that already have funding from another source and require additional funding, when this additional funding from Cures Within Reach will help improve the chances of success of the project, and therefore increase the chance of patient impact. We are open to working with other funders who share our desire to find solutions for Meniere’s disease and/or related symptoms/consequences, including tinnitus and hearing loss patients and are interested in these near-term repurposing opportunities.

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**Due Date for Project Proposal Summary Submissions**

05-26-2021