

# CureAccelerator Live! Repurposing Research to Create Patient Impact in Rare Diseases and Diversity, Equity and Inclusion

## Description / Background

Proposals are submitted on the Cures Within Reach CureAccelerator platform. Sign up as a Researcher or Clinician at <https://app.cureaccelerator.org/registration> or log into an existing CureAccelerator account at <https://app.cureaccelerator.org/home> to submit. **Additional proposal submission instructions can be downloaded at this link: <http://bit.ly/cwrcalrfp>.**

This Request for Proposals (RFP) from [Cures Within Reach](#) (CWR) is seeking **clinical repurposing trials in any rare disease from US-based Principal Investigators (PIs) to address Diversity, Equity and Inclusion, for an upcoming CureAccelerator Live! event.** CureAccelerator Live! is a philanthropic pitch event, raising awareness of and funding for innovative repurposing research projects, with **up to \$70,000 total in clinical research funding** (which includes the required 20% Institutional Match; see Important Funding Information below) for the winning project announced during the event. Up to five clinical repurposing trials will be selected to pitch at this event, likely held in Fall 2022. More specifics about the CureAccelerator Live! event to come.

Eligible submissions must **EITHER:**

- Be led by a US-based **underrepresented racial / ethnic minority PI (as defined by the NIH; Section A in <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>)**

**OR**

- **Address rare disease racial / ethnic health disparities in communities of color as defined by the NIH (see <https://www.nimhd.nih.gov/about/overview>), led by a PI of any racial / ethnic background**

**AND**

- Be interventional clinical trials using repurposed therapies, including drugs, devices, nutraceuticals and diagnostics, that are **already approved or generally recognized as safe by the FDA, EMA or other regulatory agency**
- **Focus on an unsolved rare disease** as defined by US standards as a condition that impacts fewer than 200,000 people or by European standards as a condition that impacts less than 1 in 2,000 people
- Be conducted at any **US-based accredited academic, nonprofit and governmental research institutions and/or health systems** significantly involved with medical research,

where good scientific research and clinical practices can be assured

**Any health disparities submissions for this RFP must include ideas and/or plans for engagement / collaborations with community-based organizations to engage communities of color in the clinical trial.** CWR will provide up to \$15,000 in additional financial support for community engagement, with at least \$5,000 required for community engagement. CWR recommends a range of \$7,500 - \$15,000. Ideas for possible community engagement must be included in the Research Description section of the proposal and do not count towards the suggested word length of 1,500 words. Community-based organizations are already engaged with and trusted by communities of color, and may include health-related organizations (i.e., community health centers), social services-related organizations (i.e., food banks) or other organizations (i.e., religious groups). Community engagement ideas do not need specific details at the proposal stage, and proposals will not be scored on community engagement in the review process.

**Rare disease clinical repurposing trials led by a US-based underrepresented racial / ethnic minority PI may, but are not required to, focus on health disparities.** CWR is interested in promoting Diversity, Equity and Inclusion in biomedical clinical research by 1) supporting the careers of and 2) closing the NIH funding gap for underrepresented racial / ethnic groups through funding for clinical repurposing trials led by minority PIs.

Examples of rare disease racial / ethnic health disparities clinical repurposing trials include:

- A trial in a rare disease that disproportionately impacts communities of color in incidence, prevalence or patient outcomes, and focuses enrollment on patients of color (examples: sickle cell disease, triple negative breast cancer, cerebral palsy)
- A trial in a rare disease that includes specific enrollment goals to allow for data analysis by race / ethnicity
- A trial in a rare disease recruiting patients of color exclusively

Eligible clinical repurposing trials may also:

- Test combination therapies in order to increase 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

Only interventional clinical trials lasting no more than 36 months that treat or screen patients to prevent disease progression and / or improve patient outcomes in unsolved diseases with a repurposed therapy are eligible for this round of funding. **Clinical trials focused on preventative care to prevent new disease diagnoses are not eligible for this round of funding.**

CWR is also interested in supporting both previously funded investigators and early-stage investigators and who have 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 clinical trial and the investigator.

**Repurposing innovation, feasibility of the research plan, relevance to the patient population, potential clinical impact, "value" of the research plan and the research team are key ranking criteria for a successful proposal submission.** Proposals for this RFP will be reviewed, scored and ranked by CWR's external Grant Review Committee. PIs will be contacted

in approximately 6-8 weeks following the proposal submission deadline with a decision.

**Up to five projects will be selected as finalists for the CureAccelerator Live! event.** PIs, or their designated and approved co-investigator, must be willing to make a pitch for their project either at an in-person event or at a virtual event, likely held in Fall 2022. At least one pitched project will be selected for funding at the CureAccelerator Live! event. There are currently no travel stipends or reimbursements available at this time. More specifics about the CureAccelerator Live! event to come.

All PIs selected as finalists for CureAccelerator Live! will receive consultation from CWR for the preparation of their pitch, and CWR will create a poster for the pitched project to be displayed during the event. Finalists will also provide a breakdown and justification for the total requested budget and a Research Roadmap that details the project's research objectives, timeline and success measures.

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.

While only clinical repurposing trials are eligible for this round of funding, we welcome proposals for any research stage / type, which may be considered for future funding opportunities. If you have a repurposing idea in a rare disease 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](mailto:clare@cureswithinreach.org) to discuss fit and/or submission options.

#### **Important Funding Information:**

**CWR will provide no more than 80% of the REQUESTED PROJECT FUNDING, and the institution or organization 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 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.

All funding amounts and 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; must be equal to the Requested Project Funding
- Existing Project Funding = Project Funding minus Remaining Project Funding (no set maximum)
- Requested Project Funding = funding requested through this RFP (maximum = \$70,000 for clinical research costs, including the 20% institutional match; this can be up to \$85,000 total for health disparities projects, with additional funding for community engagement)

- Budget Breakdown = breakdown of the Requested Project Funding (maximum total = \$70,000 for clinical research costs, including 20% institutional match; this can be up to \$85,000 total for health disparities projects with additional funding for community engagement)
- Estimated Overall Project Costs = Requested Project Funding (see above)

Up to 10% of the REQUESTED PROJECT FUNDING may be used for Direct Project Administration Costs. However, the total amount of Indirect Costs and Direct Project Administrative Costs combined may not be more than 20% of the REQUESTED PROJECT FUNDING. No funds provided by CWR can be used for Indirect Costs.

Any health disparities submissions for this RFP must include ideas and/or plans for engagement / collaborations with community-based organizations to engage communities of color in the clinical trial. CWR will provide up to \$15,000 in additional financial support for community engagement, with at least \$5,000 required for community engagement. CWR recommends a range of \$7,500 - \$15,000. **Community Engagement costs should be included as "Direct Project Administration Costs" in the Budget Breakdown of the submission form and do not count toward the 10% limit for Direct Project Administration costs.** Community engagement ideas do not need specific details at the proposal stage, and proposals will not be scored on community engagement in the review process.

CWR will accept REQUESTED PROJECT FUNDING amounts that are within the minimum and maximum amounts indicated. We do not set an upper limit to the total PROJECT FUNDING, or the EXISTING PROJECT FUNDING, but REQUESTED PROJECT FUNDING amounts to CWR 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 CWR maximum, and for projects that already have EXISTING PROJECT FUNDING from another source and require REMAINING PROJECT FUNDING, when this additional funding from CWR will help speed patient impact.

**CWR REQUESTED PROJECT FUNDING must be sole, late or final funding for the project.** REQUESTED PROJECT FUNDING from CWR 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 \$70,000. The PI enters \$70,000 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 \$56,000 (80%) of the REQUESTED PROJECT FUNDING and the institution will match the remaining \$14,000 (20%) of the REQUESTED PROJECT FUNDING.*

#### *Example B*

*The maximum funding request to CWR is \$70,000. The PI enters \$70,000 for REQUESTED PROJECT FUNDING and for ESTIMATED OVERALL PROJECT COSTS in the BUDGET BREAKDOWN, which will cover one-third of the \$210,000 entered for PROJECT FUNDING. The other \$140,000 is entered for EXISTING PROJECT FUNDING, and has already been secured by the investigator or institution. CWR approves this project and will provide \$56,000 (80%) of the REQUESTED PROJECT FUNDING, and the institution will match the remaining \$14,000 (20%) of the REQUESTED PROJECT FUNDING and provide the \$140,000 of the EXISTING*

## PROJECT FUNDING.

### Diseases/Conditions

Any rare disease. A rare disease is defined by US standards as a condition that impacts fewer than 200,000 people, or by European standards as a condition that impacts less than 1 in 2,000 people.

### Treatments

Any repurposed drugs, devices, nutraceuticals or diagnostics

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### Project Type

- Human Clinical Trial
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### Timeline

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#### Do you have a preference for where the research should take place?

This research must take place in the United States. This RFP is open to US-based accredited academic, nonprofit and governmental research institutions and/or health systems significantly involved with medical research, 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](mailto:clare@cureswithinreach.org) to learn more.

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#### Do you have a preference for where you would like to see patient impact?

This RFP seeks clinical repurposing trials in any unsolved rare disease, that:

- are led by a US-based underrepresented racial / ethnic minority PI (as defined by the NIH; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>)
- OR address rare disease racial / ethnic health disparities in communities of color as defined by the NIH (see <https://www.nimhd.nih.gov/about/overview>) led by a PI of any racial / ethnic background

CWR is hopeful that this RFP can help address Diversity, Equity and Inclusion in rare diseases and that any discovery would be useful anywhere in the world where the repurposed therapy is available.

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### Restrictions

There are no other restrictions other than those described above.

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## Other Information for Researchers

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CWR primarily funds 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. 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.

CWR is also interested in supporting both previously funded PIs and early-stage PIs who have 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 clinical trial and the PI.

**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 proposal submission.** Proposals for this RFP will be reviewed, scored and ranked by CWR's external Grant Review Committee, and up to 5 of the top-scoring proposals will be selected to participate in CureAccelerator Live!. PIs will receive a decision on their proposal submission within approximately 6-8 weeks of the RFP deadline.

If selected to participate in CureAccelerator Live!, the PI or their designated and approved co-investigator, must be willing to make a pitch for their project either at an in-person event or at a virtual event, likely held in Fall 2022. At least one pitched project will be selected for funding at the CureAccelerator Live! event. There are currently no travel stipends or reimbursements available at this time. More specifics about the CureAccelerator Live! event to come.

All PIs selected as finalists for CureAccelerator Live! will receive consultation from CWR for the preparation of their pitch, and CWR will create a poster for the pitched project to be displayed during the event. Finalists will also provide a breakdown and justification for the total requested budget and a Research Roadmap that details the project's research objectives, timeline and success measures.

While only clinical repurposing trial projects are eligible for this round of funding, we welcome proposals for any research stage / type, which may be considered for future funding opportunities. If you have a repurposing idea in a rare disease 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](mailto:clare@cureswithinreach.org) to discuss fit and/or submission options.

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## **Funding Available**

Minimum \$50,000

Maximum \$70,000

## **Funding Description**

See full Funding information in the Research Description section above. Any health disparities submission for this RFP must include ideas and/or plans for engagement / collaborations with community-based organizations to engage communities of color in the clinical trial. Community engagement ideas do not need specific details at the proposal stage, and proposals will not be scored on community engagement in the review process. CWR will provide up to \$15,000 additional financial support for community engagement, with at least \$5,000 required for community engagement. CWR recommends a range of \$7,500 - \$15,000. These costs should be included as "Direct Project Administration Costs" in the Budget Breakdown of the submission form and do not count toward the 10% limit for Direct Project Administration costs. CWR will accept REQUESTED PROJECT FUNDING amounts that are within the minimum and maximum amounts indicated. CWR REQUESTED PROJECT FUNDING must be sole, late or final funding for the project, as indicated in the Research Description. CWR will provide no more than 80% of the REQUESTED PROJECT FUNDING, and the institution or organization proposing the research will match at least 20% of the REQUESTED PROJECT FUNDING. The Institutional Match must be real dollars committed to the project 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; from industry (including the dollar value of donated drug); 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**

We are open to working with other funders who share our desire to find solutions for rare disease patients and/or support Diversity, Equity and Inclusion in clinical research. We will accept projects that already have funding from another source and require additional funding, when this additional funding from CWR will help improve the chances of success of the project, and therefore increase the chance of patient impact. CWR REQUESTED PROJECT FUNDING must be sole, late or final funding for the project, as indicated in the Research Description.

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## **Due Date for Project Proposal Summary Submissions**

06-06-2022

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