2025 ReGRoW: Funding for Underresourced Researchers in Low and Lower-Middle Income Countries

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CuresWithinReach

OVERVIEW

This Request for Proposals (RFP) from Cures Within Reach (CWR) is for our ReGRoW program, providing grants for clinical repurposing trials led by **underresourced researchers and clinicians based in low and lower-middle income countries (LMICs), as defined by the World Bank (see https://data.worldbank.org/products/wdi-maps),** to impact LMIC-based patients**.** This RFP is seeking clinical repurposing trials to address any unsolved disease facing patients in LMICs. CWR is interested in building capacity for clinical research in LMICs while finding available and affordable treatments for patients in LMICs through repurposing research.

While this RFP is accepting clinical repurposing trials addressing any unsolved disease, **CWR has a preference for trials that address high disease burden** (see https://ourworldindata.org/burden-of-disease) whether non-communicable diseases; communicable diseases; maternal, neonatal and nutritional diseases; or injuries.

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 **generic drugs, nutraceuticals or indigenous therapies**, as well as 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 also may be added to current standard of care to improve patient outcomes and/or quality of life.

CWR is accepting budgets of up to US$65,000 for this funding opportunity (see Important Funding Information below).

All submissions **must** include ideas and/or plans to engage the community of interest before, during and after the proposed clinical trial. This can be through collaborations with community-based organizations, community leaders and/or community-led patient groups. **CWR will provide up to US$7,500 in additional financial support for community engagement**, with at least US$4,000 required for community engagement.

All submissions for this RFP are via CWR's online grant management platform on ProposalCentral (https://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 **Repurposing Research in LMICs** program. Click on the "Apply Now" button on the right to begin a submission. For more information about CWR's funding opportunities generally, visit https://bit.ly/cwrrfps.

CWR has a 2-stage submission process, starting with the brief Letter of Intent (LOI). Full scientific details are not required at the LOI stage. LOIs for this RFP will be reviewed, scored and ranked by CWR staff, external Grant Review Committee and/or 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 March 28, 2025. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions.

FULL DESCRIPTION

Background

This RFP is seeking clinical repurposing trials led by **underresourced researchers and clinicians based in low and lower-middle income countries (LMICs), as defined by the World Bank (see https://data.worldbank.org/products/wdi-maps).** This RFP is seeking clinical repurposing research to address any **unsolved disease facing patients in LMICs.**

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

While this RFP is accepting clinical repurposing trials addressing any unsolved disease, **CWR has a preference for trials that address high disease burden** (see https://ourworldindata.org/burden-of-disease) whether non-communicable diseases; communicable diseases; maternal, neonatal and nutritional diseases; or injuries.

Repurposed therapies can include **generic drugs, nutraceuticals or indigenous therapies**, as well as combination 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, and 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 also may be added to current standard of care to improve patient outcomes and/or quality of life. Repurposed therapies may be used to create "new" treatments that:

- Reduce disease symptoms, progression or incidence; or
- Restore function lost to the disease; or
- Reduce or eliminate severe side effects of currently used therapies, thereby improving patient outcomes and quality of life

Eligible treatments must:

- Be a drug, nutraceutical or indigenous medicine used in an interventional clinical trial to treat a new disease indication
- Be already approved by the FDA, EMA or other regulatory body, or be otherwise safe and readily available for human use
- Be available in generic form in the country where the research will be conducted
- Not be under patent protection anywhere in the world

Eligible institutions must:

- Be located in LMICs, as defined by the World Bank (see https://data.worldbank.org/products/wdi-maps)
- Have received previous external, third-party clinical research funding from government, NGO, private foundation or other sources

- Have a research Institutional Review Board (IRB), Ethics Review Committee or equivalent in place
- Follow the World Health Organization's or other regulatory agencies' standards for Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and/or Good Laboratory and Clinical Practice (GLCP)
- Have past or current experience with human clinical research
- Preference will be given to institutions with established collaborations with institutions in high income countries

Eligible submissions must:

- Be submitted and conducted by PIs located in LMICs, as defined by the World Bank (see https://data.worldbank.org/products/wdi-maps)
- Address any unsolved disease or medical condition, with a preference for addressing high disease burden (see https://ourworldindata.org/burden-of-disease) whether non-communicable diseases; communicable diseases; maternal, neonatal and nutritional diseases; or injuries
- Be interventional human clinical trials that treat patients with a repurposed therapy to prevent disease progression and/or improve patient outcomes in unsolved diseases; preference will be given to clinical trials supported by strong scientific evidence or clinical observations
- Be completed in no more than 36 months
- Be submitted in English only via ProposalCentral
- 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

Community Engagement: All submissions **must** include high level, general ideas and/or plans to engage the community of interest before, during and after the proposed clinical trial; one or two sentences at a minimum. Full details are not required for the LOI and LOIs will not be scored on community engagement ideas/plans. Community engagement can be through collaborations with community-based organizations, community leaders and/or community-led patient groups. **CWR will provide up to US$7,500 in additional financial support for community engagement**, with at least US$4,000 required for community engagement. This funding is to be spent internally at the research institution or to be paid externally to the community-based organizations supporting the trial.

Our strongest preference is for proof of concept, pivotal, Phase I or Phase IIA clinical repurposing trials supported by strong preclinical evidence, real world evidence, AI/ML drug-disease matching tools and/or clinical observations. CWR may also consider later stage clinical trials that require additional funding. CWR is open to all clinical trial designs (open label, cross-over, dose determination, randomized, blinded, controlled, etc.) that have the opportunity to create robust and well-defined outcomes 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.

If you have a repurposing idea to impact patients in LMICs that isn't an exact fit for this RFP, or if you have eligibility questions, please contact Clare Thibodeaux, PhD at clare@cureswithinreach.org to discuss fit and/or submission options.

Important Funding Information

Specific budget definitions for different types of costs can be found in the Letter of Intent (LOI) submission instructions on ProposalCentral.

All funding requests are in US dollars. **CWR is accepting budgets of up to US$65,000 for clinical repurposing trials**, and CWR is waiving the usual 20% institutional funding match required by CWR for this RFP. Therefore, CWR will provide 100% of the submitted project budget. Up to 20% of the submitted project budget may be used for indirect costs. A detailed budget is not required at the LOI stage. CWR is also providing **up to US$7,500 in additional financial support for community engagement**, with at least US$4,000 required for community engagement activities.

The total budget 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. Below are some general examples:

- The clinical trial will cost US$65,000 to complete, and the maximum budget amount of the RFP is US$65,000. This clinical trial is eligible for funding from CWR.
- The clinical trial will cost US$195,000 to complete, and the maximum budget amount of the RFP is US$65,000. The PI has already secured US$130,000 in existing funding / support. This clinical trial is eligible for funding from CWR.
- The clinical trial will cost US$195,000 to complete, and the maximum budget amount of the RFP is US$65,000. The PI has already secured US$0 in existing funding / support. This clinical trial 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 a desire to fund underresourced PIs located in LMICs and are interested in these near-term repurposing opportunities. **CWR will accept projects that already have funding from another source when additional funding from CWR will help improve the chances of success of the project and therefore increase the chance of patient impact.**

LOI Submission and Due Date

All submissions for this RFP are via CWR's online grant management platform on ProposalCentral (https://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 **Repurposing Research in LMICs** program. Click on the "Apply Now" button on the right to begin a submission.

The LOI submission deadline is 11:59pm U.S. Eastern Time on March 28, 2025. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions/issues about the LOI submission deadline. For more information about 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 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, external Grant Review Committee (representing research, industry, clinicians, nonprofits, government and the patient/community voice) and/or CWR's 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.