Impacting Blood Cancers through Clinical Repurposing Trials – 2024

CUREACCELERATOR®
funding from
CuresWithinReach

OVERVIEW

This Request for Proposals (RFP) from Cures Within Reach (CWR) is seeking **clinical repurposing trials to address unsolved blood cancers, with a preference for trials impacting multiple myeloma and/or myelodysplastic syndromes.** We are interested in generic or proprietary approved 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) reduce or eliminate severe side effects of currently used therapies for any blood cancer, 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 may include **drugs, devices, nutraceuticals, diagnostics or cellular/gene 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 the clinic 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 $75,000 for this RFP, which includes the required institutional match (see Important Funding Information below). Specific budget definitions for different types of costs can be found in the Letter of Intent (LOI) submission instructions on ProposalCentral. For Principal Investigators (PIs) who are interested in including underrepresented patients (as defined by the NIH) in the proposed clinical trial, CWR may provide an optional $5,000 - $15,000 in additional financial support for approved community engagement costs. Interested PIs may include any ideas and/or plans for engagement / collaborations with community-based organizations to engage underserved communities in the clinical trial. However, community engagement is not required, and community engagement costs should not be included in the requested funding amount submitted to CWR in the LOI. If a clinical trial is selected for funding, CWR will contact the PI about potential community engagement.

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. Although start-ups, biotechs, pharmaceutical companies and medical device companies are not eligible for this RFP, their collaborators at eligible institutions can apply.

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. Click on the "Apply Now" button on the right to begin a submission. For LOI submission instructions and more information about CWR's funding opportunities generally, visit https://bit.ly/cwrrfps.

CWR has a 2-stage submission process, starting with the LOI. Full scientific details are not required at the LOI stage. 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. 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 July 29, 2024. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions.

FULL DESCRIPTION

Background

This RFP from CWR is seeking **clinical repurposing trials to address unsolved blood cancers, with a preference for trials impacting multiple myeloma and/or myelodysplastic syndromes.** We are interested in generic or proprietary approved 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) reduce or eliminate severe side effects of currently used therapies for any blood cancer, thereby improving patient outcomes and quality of life.

Repurposed therapies can include drugs, devices, nutraceuticals, diagnostics or cellular/gene 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.

An unsolved blood cancer 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

Eligible submissions must:

- Be interventional clinical trials addressing blood cancers, with a preference for multiple myeloma and/or myelodysplastic syndromes, repurposing approved drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies in a new indication
- 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

Eligible submissions may:

- Test combination therapies to increase the impact on patient outcomes and/or quality of life, including combining the current clinical standard of care with a repurposed treatment or combining multiple repurposed therapies
- Repurpose therapies approved for use in adults into pediatric indications, or vice versa

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. We 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 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.

If you have a repurposing idea in blood cancers 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**.

Important Funding Information

All funding requests are in US dollars. CWR is accepting budgets of up to $75,000 for clinical repurposing trials, 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.**

For example, if the total funding amount submitted to CWR is $75,000, CWR will provide 80% or $60,000, and the research institution will provide 20% or $15,000. 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, CWR will contact the PI and the research institution about this requirement.

The 20% institutional match must be real dollars committed to the project. 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:

- The project will cost $75,000 to complete, and the maximum funding amount of the RFP is $75,000. This project is eligible for funding from CWR.
- The project will cost $225,000 to complete, and the maximum funding amount of the RFP is $75,000. The PI has already secured $150,000 in existing funding / support. This project is eligible for funding from CWR.
- The project will cost $225,000 to complete, and the maximum funding amount of the RFP is $75,000. The PI has already secured $0 in existing funding / support. This project is not eligible for funding from CWR.

Specific budget definitions for different types of costs can be found in the LOI submission instructions on ProposalCentral. Note: detailed project budgets are not required at the LOI stage.

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 treat blood cancers and are interested in these near-term repurposing opportunities. **We will accept LOI submissions that already have funding from another source, when additional funding from CWR will help improve the chances of success of the clinical trial, and therefore increase the chance of patient impact.**

LOI Submission and Due Date

All submissions for this RFP are via 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. Eastern Time on July 29, 2024. 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, "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 (representing research, industry, clinicians, nonprofits, government and the patient / community voice) 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.