

REQUEST FOR PROPOSALS

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Grand Challenges Canada[®]
Grands Défis Canada

BOLD IDEAS WITH BIG IMPACT[®]

Transition to Scale

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Executive Summary

In this Request for Proposals, Grand Challenges Canada seeks to support the transition to scale and sustainability of **Bold Ideas with Big Impact**®.

Grand Challenges Canada invests from \$100,000 up to \$1.0 million CAD to catalyze the scale and sustainability of the most promising global health innovations. To date, Grand Challenges Canada has invested more than \$62 million CAD to transition over 60 innovations in 26 countries. We look for **Integrated Innovation**® approaches, defined as the coordinated application of scientific / technological, social and business innovation that have significant potential for future health outcomes and a path to financial sustainability. Innovations must be relevant to low resource settings and target poor, marginalized populations of low- or middle-income countries.

Transition-to-Scale applicants may include innovators previously or currently funded as part of the seed (proof-of-concepts) programs of Stars in Global Health, Saving Lives at Birth, Saving Brains, or Global Mental Health. External applicants may come from Grand Challenges Canada partners, including the Every Woman Every Child Innovation Marketplace, and must be invited to apply at the sole discretion of Grand Challenges Canada.

At Transition-to-Scale, we fund the refinement, testing and implementation of bold ideas with a path to achieving **sustainable impact at scale**. Grand Challenges Canada welcomes applicants whose path to scale consists of more traditional business models via the private sector (i.e. commercialization of products / technologies). We also welcome applicants whose path to scale will be achieved via long term funding by public and/or non-profit institutions (e.g., governments and civil society organizations). In these cases, government integration and/or uptake by established national or international non-governmental organizations are considered to be the primary goal of the Transition-to-Scale process. Our main goal is to catalyze scale and sustainability – so that the bold ideas we support are closer to having big impact in a sustainable manner by the end of the Transition-to-Scale funding.

Grand Challenges Canada utilizes an array of risk capital, including grants, conditionally repayable grants, interest-free and interest-bearing loans, and convertible debt at Transition-to-Scale. We work with innovators and other funders to identify the form of capital that will be most useful and appropriate for the sustainable health of the organization or intervention. Innovators are required to secure matching funding (i.e. 1:1 match to Grand Challenges Canada contribution) ideally from a “smart partner” who can help to scale the innovation via their distribution channels, local knowledge, etc. Though it is strongly preferred, secured commitment of matched funds may not be required at the time of application.

Grand Challenges Canada will evaluate Transition-to-Scale applicants based on their use of an integrated innovation approach, demonstration of proof of concept and potential for future health outcomes, entrepreneurship, smart partners and sustainability, and commitment to achieving meaningful access and outcomes for poor, marginalized populations in low- and middle-income countries.

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1. Introduction

1.1 GRAND CHALLENGES CANADA

Grand Challenges Canada is dedicated to supporting **Bold Ideas with Big Impact®** in global health. We are funded by the Government of Canada and we support innovators in low- and middle- income countries (LMICs) and Canada. The bold ideas we support integrate science and technology, social and business innovation to find sustainable solutions to health challenges. We call this Integrated Innovation®. We have a determined focus on results and on saving and improving lives.

We know that no individual project will be able to solve a global health challenge on its own, which is why we fund a portfolio of solutions. Grand Challenges Canada funds innovator-defined challenges through our Stars in Global Health program and targeted challenges through Saving Lives at Birth, Saving Brains and Global Mental Health programs. We also source innovations through approved partners such as the Every Woman Every Child Innovation Marketplace – by invitation only. We help transition promising innovations to scale and sustainability through our Transition-to-Scale program.

Grand Challenges Canada works closely with Canada's International Development Research Centre (IDRC), the Canadian Institutes of Health Research (CIHR), and Global Affairs Canada (GAC) to catalyze scale, sustainability and impact.

Our vision is: **Bold Ideas. Big Impact. A Better World.** Our mission is: **Saving and improving lives in LMICs through Integrated Innovation.** Our primary priority is: **Solving critical global health challenges.**

1.2 BACKGROUND

Each year, millions of individuals, families and communities suffer from preventable death and illness, as a result of critical health challenges. The facts are staggering:

- In the 72 hours around the time of birth, 150,000 women and 1.6 million children die, and 1.2 million stillbirths occur, each year. Many of these deaths are preventable.
- 200 million children fail to reach their full developmental potential because of malnutrition, infection, prematurity and lack of nurturing. Again, much of this failure is preventable with appropriate interventions and treatment.
- Mental health conditions represent about 14% of the total global burden of disease, with a significant portion of this burden in LMICs, where there are very limited options for treatment.
- In 45 countries around the world, less than half of the population has access to adequate sanitation facilities. Approx. 700,000 children die every year from diarrhea caused by unsafe water and poor sanitation.
- For a majority of the 800 million girls and women between the ages of 15 and 49 who are menstruating on any given day, there continue to be barriers to accessing high-quality menstrual hygiene management, such as lack of

- menstrual or reproductive health education or knowledge, cultural stigma around menstruation and lack of affordable, quality menstrual products.
- Globally, around 1.0 billion people live with some form of disability. Of this, the World Health Organization estimates that approx. 30 million people in LMICs require prosthetic limbs, braces, or other devices and that only 3% have access to rehabilitation services and assistive devices.

Despite these critical challenges, there is reason for hope. The talent in Canada and in LMICs that can be mobilized to tackle these issues is vast. By supporting a wide range of innovators, Grand Challenges Canada aims to play a big role in the development and global health communities. Our goal is to spur economic opportunities and widespread health benefits, fostering local health innovations that are affordable and scalable in locations where they are needed the most.

At the core of our operating philosophy is Integrated Innovation, the coordinated application of scientific / technological, social and business innovation to develop solutions to complex challenges that can achieve sustainable impact at scale. This approach does not discount the singular benefits of each of these types of innovation alone, but rather highlights the powerful synergies that can be realized by aligning all three. For more information, please see: www.grandchallenges.ca/integrated-innovation

See www.grandchallenges.ca for information on our funding programs, and www.grandchallenges.ca/our-innovators to see what we have funded to date.

2. Approach

2.1 PROGRAM SCOPE

For our Transition-to-Scale program, Grand Challenges Canada seeks **Integrated Innovations** from our Stars in Global Health, Saving Lives at Birth, Saving Brains, and Global Mental Health programs, as well as invited innovations from approved partners, such as the Every Woman Every Child Innovation Marketplace. Please note that applicants whose innovation has not yet been funded by Grand Challenges Canada are by invitation only at the sole discretion of Grand Challenges Canada.

The Transition-to-Scale program seeks innovations that are bold and have the potential to make a substantial impact on a global health problem. We are looking for affordable approaches that can be used effectively to improve health in communities in LMICs with no or limited healthcare infrastructure (e.g., lack of electricity or clean water, etc.) and limited pools of trained personnel. We also look for approaches that reflect an understanding of the target user market, address the needs of the user(s), and can be easily assimilated into cultural practices.

2.2 SCALE AND SUSTAINABILITY

The Transition-to-Scale program supports innovators who are positioned to scale their global health solutions. While many of our investments are geared toward bringing an

idea or prototype to market, i.e. commercialization of products / technologies and dissemination of transformative innovations or services, the path to scale and sustainability for many innovations is through public channels. We welcome innovations geared toward either type of scaling pathways, described further below.

Social Enterprise Models

Social entrepreneurs are individuals with innovative solutions to society's most pressing problems. They are ambitious and persistent, tackling major social issues and offering new ideas for wide-scale change¹. Whereas business entrepreneurs typically measure performance in profits, social entrepreneurs also take into account a positive return to society. Grand Challenges Canada believes social entrepreneurship is a critical feature to enable scaling, sustainability and the ultimate achievement of impact. Grand Challenges Canada defines success of Transition-to-Scale funding for social enterprises as achieving financial sustainability while causing positive health impacts at scale in order to 1) grow organically without outside financial intervention or 2) build a business that is attractive to other entities for merger, acquisition and joint venture activities to occur so that combined they continue to serve their intended markets. Both non-profit and for-profit social enterprises are strongly encouraged to apply to this Request for Proposals.

Public Health Models

For many innovative interventions and service delivery models, the route to scale and sustainability will be achieved via long term funding by public and/or non-profit institutions. In these cases, Grand Challenges Canada defines successful Transition-to-Scale as achieving integration into government-run services, including government funding to sustain the service, and/or uptake of the model by large established national or international non-governmental organizations.

2.3 PARTNERSHIPS

Given the complexity of the problems that exist in global health and low-resource settings, it is not feasible or desirable to expect that Grand Challenges Canada alone will be able to take its seed grantees from initial funding through to scale-up, including the eventual commercialization and/or dissemination of their transformative innovations. As a result, a key component of Transition-to-Scale is *partnerships*.

In order to successfully scale up promising innovations, Grand Challenges Canada encourages partnerships with a number of actors, including social angel investors, small and medium-sized companies, multinationals, foundations, philanthropists, not-for-profits, multilateral organizations and public sector entities, including departments and agencies. Innovators need to include required partnerships to optimize sustainability and impact in their plans for transition to scale.

¹ https://www.ashoka.org/social_entrepreneur

To enable and leverage partnerships, the following principle guides Grand Challenges Canada funding: Transition-to-Scale proposals require 1:1 matching funds (i.e., 1:1 match of partner funds to Grand Challenges Canada funds) through partnerships to be eligible for Grand Challenges Canada funding.

Innovators are required to secure matching funding ideally from a “smart partner” who can help to scale the innovation via their distribution channels, local knowledge, entrepreneurial experience, etc. Though it is preferred, secured commitment of matched funds may not be required at the proposal stage and Grand Challenges Canada may be able to make approval decisions without the matched funding in place. However, innovators must identify the smart partners that they intend to work with in their proposals, and will ultimately need to secure matching funds in order for us to move forward and disburse funding. Please also note that we will be unable to consider Government of Canada federal funds as matching funding.

On a case-by-case basis, Grand Challenges Canada reserves the right to determine the extent to which the 1:1 matching funds principle is applied. Matching funds should be ‘new cash’. Where cash is not possible, and where strong “smart partners” are present such as government or corporate partners, matching through in-kind contributions will be considered by Grand Challenges Canada on a case by case basis.

2.4 FINANCING AMOUNT, STRUCTURE, AND TERM

Contingent upon 1:1 matching funds through partnerships and the needs of the Transition-to-Scale activities, Grand Challenges Canada may provide awardees up to \$1.0 million CAD for a defined period of time depending on availability of funds to Grand Challenges Canada. Please note that unless all evaluation criteria (see Section 4.5) are strongly met, funding in the \$100,000 to \$500,000 range CAD is much more likely.

Potential instruments for investment include grants, repayable grants, interest-free loans, interest-bearing loans, convertible debt, pay-on-results contracts, or a combination thereof. Grand Challenges Canada works with innovators and other funders to identify the form of capital that will be most useful and appropriate for the sustainable health of the organization or intervention. The choice of investment structure is informed by (i) the organization’s stage and path to scale (e.g. for-profit or non-profit), (ii) the structure’s ability to attract additional sources of capital, including private partners, as follow-on investors, (iii) the potential effect on the intervention’s impact and on the organization’s sustainability, including its ability to become self-sustaining, (iv) the desire to encourage return of taxpayer funds when investments scale successfully and profitably, and (v) the program through which a given investment is made.

Grand Challenges Canada reserves the right to negotiate any of the above financing instruments, and to make limitations on the time, scope and amount of funding provided, at Grand Challenges Canada’s discretion.

2.5 ENVIRONMENTAL SUSTAINABILITY, GENDER EQUALITY, AND GOOD GOVERNANCE (EG2)

Grand Challenges Canada is committed to the furthering the principles of environmental sustainability, gender equality and good governance as follows:

- 1. Environmental Sustainability:** Grand Challenges Canada requires that applicants commit to ensuring that the innovation will not have material adverse environmental effects including, but not limited to, long-term and cumulative effects. Where possible, applicants should incorporate having positive environmental effects throughout the project.
- 2. Gender Equality:** Grand Challenges Canada is committed to furthering principles of gender equality in the innovations it funds. More specifically, Grand Challenges Canada is supportive of the following objectives: (1) advancing women's equal participation with men as decision-makers in shaping the sustainable development of their societies; (2) supporting women and girls in the realization of their full human rights; and (3) reducing gender inequalities in access to and control over the resources and benefits of development. We believe that supporting gender equality and the rights of women and girls is an important objective in and of itself, and that by considering gender in the development of innovations, sustained impact can be bolstered.
- 3. Good Governance:** Grand Challenges Canada is committed to furthering principles of good governance in the innovations it funds. This includes the promotion of good governance principles of participation, inclusion, equity, transparency, accountability, efficiency and effectiveness in the applicant's project.

Transition-to-Scale innovators are required to commit to compliance with the Grand Challenges Canada policy regarding these cross-cutting themes.

2.6 GLOBAL ACCESS, DATA ACCESS, AND ETHICS

Grand Challenges Canada is committed to fostering meaningful access to supported innovations for the target beneficiaries of each funded project, particularly those beneficiaries among the marginalized and poor in low- and middle-income countries; to promoting prompt and open dissemination of research findings and data arising from funded activities; and to ensuring that funded research is conducted in a manner that complies with relevant ethical standards. These commitments are embodied in Grand Challenges Canada's Global Access Policy, Data Access Policy, and Ethics Policy, which should be carefully reviewed by all applicants.

- 1. Global Access:** Grand Challenges Canada is committed to ensuring that (1) funded innovations will be made meaningfully accessible, both in terms of price and availability, to the target beneficiaries of each funded project, particularly those among the marginalized and poor in low- and middle-income countries, (2) knowledge and information gained through funded projects will be disseminated

broadly and promptly to the global research community and beyond, and (3) commercialization of funded innovations is encouraged, so long as it is consistent with these principles.

- 2. Data Access:** Grand Challenges Canada is committed to ensuring that (1) data will be shared as broadly and as promptly as possible to foster innovation and optimize prospects for the translation of knowledge into life-saving solutions, (2) respect for attribution, cultural diversity, scientific integrity, and the privacy of individuals and communities that contribute data will be appropriately considered in all data access activities, (3) collection, production, sharing and use of data will be consistent with applicable laws, regulations, and standards of ethical research conduct, (4) the individuals and communities who enable and support inquiry, particularly those in low- and middle-income countries, be they research participants or investigators, benefit from data to the extent possible.
- 3. Ethics:** Grand Challenges Canada requires that (1) research involving human participants be conducted in a manner that demonstrates, protects and preserves respect for persons, concern for the welfare of individuals, families and communities, and justice, (2) research involving animals be conducted in a manner that ensures their humane care and treatment, and (3) certain research endeavours, including but not limited to research with recombinant DNA, biohazards and genetically modified organisms, be subject to enhanced regulation and oversight as appropriate.

Transition-to-Scale innovators are required (1) to commit to compliance with the above policies, (2) to ensure that intellectual property rights, including those of third parties, do not impede meaningful access to innovations and widespread dissemination of knowledge, (3) to develop a specific plan for implementation of the Global Access Policy and Data Access Policy (the “Action Plan”), and (4) to enter into separate agreements that grant Grand Challenges Canada rights in project data, as well as certain rights in innovations if meaningful access is not attained (the “Global Access Agreements”). Further information on these requirements is provided below.

2.7 APPLICANTS ALIGNED WITH A TARGETED CHALLENGE

Saving Brains

Projects aligned to the Saving Brains grand challenge of improving child development are expected to demonstrate large-scale real-world impact on early brain development. To this end, projects aligned to Saving Brains should have demonstrated impact on child development in the proof of concept stage.

To establish a shared language for the discussion and comparison of results across projects in the Saving Brains portfolio, a set of core outcome metrics has been developed. Use of metrics to capture core outcomes should therefore be incorporated into project proposals. All projects should include at least one metric in each of the following domains: 1) physical growth, 2) gross/fine motor skills, 3) cognitive function 4) receptive language and expressive language 4) socioemotional capacities. This set of

core outcome metrics serves as a minimum set and does not limit the scope of outcomes that can be captured and measurement of additional outcomes relevant to specific hypotheses is expected. All projects should have monitoring and evaluation systems in place to clearly quantify effects on early brain development, identify shortcomings and maximize impact.

Saving Lives at Birth

Projects aligned to Saving Lives at Birth are focused on the prevention of maternal and newborn deaths and stillbirths. At proof of concept, project results should have demonstrated improved health outcomes and/or expanded access to quality care around the time of birth for pregnant women, mothers and/or newborns.

At the Transition-to-Scale phase, projects aligned to the Saving Lives at Birth grand challenge are expected to further demonstrate large-scale real-world impact in one or more of the following areas: 1) Decreased neonatal mortality rate 2) Decreased institutional neonatal mortality rate 3) Decreased neonatal morbidity incidence/prevalence rates 4) Decreased neonatal morbidity case fatality rates 5) Decreased institutional maternal mortality ratio 6) Decreased direct obstetric case fatality rate 7) Decreased maternal morbidity incidence/prevalence rates 8) Decreased maternal morbidity case fatality rates 9) Decreased stillbirth rate 10) Decreased intrapartum stillbirth rate 11) Decreased intrapartum and very early neonatal death rate 12) Decreased low birth weight rate 13) Decreased preterm birth rate 14) Increased demand for family planning satisfied 15) Increased coverage of antenatal care (four or more visits) 16) Increased coverage of skilled attendant at delivery 17) Increased coverage of early postnatal visit for mothers and babies 18) Increased coverage of thermal/newborn care 19) Increased coverage of exclusive breastfeeding 20) Increased coverage of early initiation of breastfeeding

It is expected that innovators will only be able to collect and report on a selection of the prioritized indicators listed above, given the difficulty in rigorously evaluating mortality impacts. These metrics serve as a minimum set for consideration and does not limit the full scope of outcomes that could be captured. Measurement of additional outcomes is expected. All projects should have monitoring and evaluation systems in place to clearly demonstrate outcomes, identify shortcomings, and maximize impact.

Global Mental Health

Projects aligned to Global Mental Health should have demonstrated the ability to improve treatments and expand access to evidence based care for people living with mental illness at the proof of concept stage.

At the Transition-to-Scale phase, projects aligned to the Global Mental Health grand challenge are expected to further demonstrate large-scale real-world impact in one or more of the following areas: 1) Integrate screening and core packages of services into routine primary health care 2) Reduce the cost and improve the supply of effective medications 3) Provide effective and affordable community-based care and rehabilitation

4) Improve children's access to evidence-based care by trained health providers 5) Develop effective treatments for use by non-specialists, including lay health workers with minimal training 6) Incorporate functional impairment and disability into assessment 7) Develop mobile and IT technologies (such as telemedicine) to increase access to evidence-based care 8) Develop mental health treatments and service delivery models for humanitarian contexts.

To establish a shared language for the discussion and comparison of results across projects in the Global Mental Health portfolio, a set of core outcome metrics has been developed (http://www.grandchallenges.ca/wp-content/uploads/20160311_CoreMetrics_RFP_EN.pdf). Projects will be expected to report against these where applicable. These metrics serve as a minimum set and does not limit the scope of outcomes that can be captured and measurement of additional outcomes is expected. All projects should have monitoring and evaluation systems in place to clearly demonstrate outcomes, identify shortcomings and maximize impact.

3. Activities and Deliverables

Innovators funded under this effort will be expected to engage in the activities and provide the specific deliverables listed below, which will help to demonstrate project progress and success:

1. Quarterly progress reporting, focused on utilization of funds, performance (as measured through the Performance Measurement Framework (PMF)) and outcomes achieved, including periodic written progress reports and conversations via teleconference, monitoring & evaluation plans, impact assessments, theories of change and reporting against core metrics where applicable, working with Grand Challenges Canada on projections of future health impacts, etc. Please note that funds may only be advanced to innovators to cover budgeted expenses for a period of two quarters, and that advances to cover the budgeted expenses for a third quarter will be contingent on the first quarter being fully accounted for.
2. Dissemination of knowledge, including through social media, open access publications, depositing of data into publicly accessible repositories, press releases, conferences, stakeholder engagement, etc.
3. A final report that accounts for financial expenditures and that captures a clear assessment of the impact of the project, including progress towards achieving meaningful access to innovations and widespread dissemination of knowledge. Please note that a 5% hold back of funds will be applied to all funding under this program, to be released to innovators upon project completion and full justification of costs.
4. Continued post-investment updates on management of intellectual property rights in supported innovations and on progress in implementing global access and data access Action Plans.

Instructions for reporting will be provided to successful recipients.

In addition to the above-mentioned activities, innovators will be expected to:

1. Participate in public engagement activities
2. Contribute to the learning agenda for specific challenges, including through participation in meetings with other Grand Challenges Canada innovators.

Please note that funded innovators may be audited by Grand Challenges Canada, Global Affairs Canada, and/or the Auditor General of Canada at any time up until the end of 2028, which will be reflected in their funding agreements.

4. Rules and Guidelines

Grand Challenges Canada's Board of Directors makes the final funding decisions with recommendations, where applicable, from Grand Challenges Canada's Investment Committee. Peer reviewers sourced through the Canadian Institutes of Health Research provide input, where applicable, to Grand Challenges Canada and the Investment Committee. Depending on the nature of the Transition-to-Scale opportunity, Grand Challenges Canada may exercise its discretion to determine the appropriate review and approval process.

4.1 ELIGIBILITY CRITERIA

1. The applicant must be a non-profit organization, for-profit company, or another recognized institution that is incorporated in an eligible jurisdiction, as listed in Appendix A, and is capable of receiving and administering funding. Please note that Grand Challenges Canada must approve any changes in applicant organization from the originally-funded grant.
2. The applicant must (a) be a previous or current grantee of Grand Challenges Canada or (b) be invited by Grand Challenges Canada to apply. Grand Challenges Canada reserves the right to extend invitations to external applicants who align with Grand Challenges Canada priorities, at its sole discretion.
3. Applicants funded by Grand Challenges Canada must have completed their seed grant, have demonstrated proof of concept by presenting sufficient and credible evidence to substantiate that your idea has demonstrated improved health outcome(s) and/or the reduction of significant barrier(s) to health and demand for the solution in a controlled or limited setting and have a plan to transition to scale. Applicants must propose Transition-to-Scale activities that are continuations of, or build upon, their seed grants.
4. Transition-to-Scale agreements require 1:1 matching through partnerships to be eligible for Grand Challenges Canada funding. Grand Challenges Canada reserves the right to determine the extent to which the 1:1 matching funds from partnerships are deemed acceptable. Matching funds should be 'new cash'. Where cash is not possible, and where strong "smart partners" are present such as government or corporate partners, matching through in-kind contributions will

be considered by Grand Challenges Canada on a case by case basis. Grand Challenges Canada will not match other Government of Canada federal funds. Though it is preferred, secured commitment of matched funds may not be required at the proposal stage.

5. A majority of the applicant's activities and budget must be carried out/spent in an eligible country (or countries) listed in Appendix A. If the nature of the proposal means that a significant amount funding will not be spent in one of these eligible jurisdictions, applicants must provide strong reasoning and convincing arguments that ultimately the proposal will benefit people in those countries.

4.2 APPLICATION INSTRUCTIONS

Only applicants that satisfy all the Eligibility Criteria outlined in Section 4.1 above should apply for Transition-to-Scale funding.

Please see www.grandchallenges.ca/grand-challenges/transition-to-scale for all application guidelines, submission instructions, and forms. Applications can be submitted in either English or French, or both. Applications in other languages will not be considered.

To be considered for a Transition-to-Scale investment (\$250,000 up to \$1.0 million CAD), applicants are required to submit the following:

- Health Impacts Questionnaire
- Scale and Sustainability Questions, and business / development plan, if available

As part of the due diligence process, applicants will be required to submit the following:

- A Project Framework and Results-based Management and Accountability Framework (RMAF) outlining expected outputs and outcomes of the project. Successful applicants will also be required to develop a Performance Management Framework (PMF) outlining performance indicators that will be used to measure performance in achieving outputs and outcomes of the project
- A detailed budget, including the reference to the use of the matching funds and Grand Challenges Canada funds to achieve the milestones of the project – this includes letters of support/funding from matching partners, if available
- Environmental sustainability, gender equality and good governance (EG2) questionnaire
- A completed Intellectual Property, Global Access and Data Access questionnaire, including an Action Plan to achieve meaningful access to funded innovations and widespread dissemination of knowledge, and materials relating to relevant intellectual property rights.
- Other supporting materials and documents requested by Grand Challenges Canada, including, but not limited to curriculum vitae (CV) of the innovator and key personnel, most recent annual financial statements, marketing collateral, etc.

Applicants are encouraged to access Grand Challenges Canada's Online Proposal Development Resource at www.grandchallenges.ca/proposaldevelopment which contains material to help researchers and innovators around the world develop their project proposals and plan for how their innovation will go to scale, be sustained and have impact globally.

Please note that applicants are responsible for notifying their affiliated organization/institution(s) upon application for Transition-to-Scale investment.

4.3 APPLICATION SCHEDULE

Grand Challenges Canada will accept applications on a rolling basis. Grand Challenges Canada will aim to provide a funding decision within six months of submission of a Transition-to-Scale application.

4.4 REVIEW PROCESS

Transition-to-Scale Review Process

Grand Challenges Canada will screen proposal submissions and supplementary materials based on the Eligibility and Investment Criteria outlined in Sections 4.1 and 4.5, respectively. Based on this evaluation, Grand Challenges Canada will elect which applications to move forward with. Please note that this screen and subsequent parts of the review and due diligence process will also take into account the applicant's performance on other projects funded by Grand Challenges Canada.

Due Diligence

Due diligence is conducted on health impact, operations, finances, technical parameters, intellectual property, and partnerships. Due diligence may include interviews with applicants, partners, advisors and third-party stakeholders. Funding recommendations will be made based on findings from the extensive due diligence process, a CIHR-managed independent scientific review (if applicable; described below) and input from the Grand Challenges Canada team. Grand Challenges Canada, on a case by case basis, may choose to recommend applicants who do not meet all the Investment Criteria for funding of a lesser amount to focus on a few key areas necessary to transition to scale. To inform final decision making, Grand Challenges Canada will draft an investment memo that explains the rationale for funding and will work with the innovator to refine and structure the investment during the due diligence process. At its discretion, Grand Challenges Canada may choose not to put forward applicants for a funding decision due to information that arises in due diligence or any perceived weaknesses based on the Investment Criteria.

CIHR-managed Independent Scientific Review

A Health Impacts Questionnaire will be evaluated through a scientific peer review managed independently by CIHR based on the Independent Scientific Review Criteria outlined in Section 4.5. CIHR identifies peer reviewers with global health experience and scientific expertise related to the innovation proposed in the Health Impact Questionnaire. Grand Challenges Canada will consider reviewer comments and

concerns during the due diligence process and/or deal negotiations including milestones and risk mitigation strategies. The result of this review is an important input to the recommendations put forward by Grand Challenges Canada management, the Investment Committee (if applicable) and during the final funding decisions.

Funding Decisions

Final funding decisions are made by the Grand Challenges Canada Board of Directors. Where applicable, recommendations for funding to the Board of Directors are made by the Investment Committee after review of the investment memo, results of scientific peer review, and other available information, such as brief interviews with the innovator. Recommendations for funding include: fund as recommended with additional / modified conditions; fund as interim financing to address concerns; invite to re-apply at a future date; or, reject proposals in their entirety with no invitation to re-apply.

Once projects are approved for funding, Grand Challenges Canada will then conduct additional due diligence and negotiate an investment. Refinements to the proposed project plan, structure, amount, type of funding and oversight may be required, based on the results of the review committee.

Please note that prior to being considered for funding, the Environmental Sustainability, Gender Equality and Good Governance (EG2) Questionnaire will be reviewed by an Environmental Consultant and a Gender Consultant. Consultant input and recommendations may be included as milestones and/or part of investment structuring, at the discretion of Grand Challenges Canada.

4.5 EVALUATION CRITERIA

Independent Scientific Review Criteria

An independent scientific review will evaluate, where applicable, the Health Impacts Questionnaire based on the criteria below. Reviewers are requested to provide their input and recommendations regarding ways to improve or modify the proposal.

1. How meaningful of an impact will the innovation have on the identified health challenge?
2. Has the innovator presented sufficient and credible evidence to substantiate that their idea has demonstrated improved health outcome(s) and/or the reduction of significant barrier(s) to health, and demand for the solution in a controlled or limited setting?
3. If the innovation reaches the people who need it, will it have an important impact on each individual reached?
4. Is the plan to monitor and evaluate health impacts sufficiently robust to draw the appropriate conclusions by the end of the funding?
5. Have the other elements that need to be in place for the innovation to lead to lives saved or improved been sufficiently considered in the approach?
6. Does the innovation represent more than an incremental improvement over current approaches?

7. Is the expertise and the compliment of the team appropriate to deliver on the projected health impact?

Investment Criteria

In addition to the above criteria, Transition-to-Scale investment opportunities will be evaluated by Grand Challenges Canada and its Investment Committee, where applicable, based on the following criteria:

1. **Integrated Innovation** – How strong is the coordinated application of scientific/technological, social and business innovation to maximize the likelihood of going to scale and achieving sustainable impact at scale?
2. **Impact** – What is the potential for future health outcomes in addressing a global health challenge?
3. **Entrepreneurship** – Does the team have the capacity, skills and ability to implement on their proposed vision and strategy?
4. **Smart Partnerships** – Does the team have sufficient strategic alliances and/or partnerships that will enable scaling of the innovation?
5. **Sustainability** – Is there a viable path to reach financial sustainability via private and/or public channels (without further funding from Grand Challenges Canada)?
6. **Intended Scope of Work** – Are the scope of the proposed plan and the funds requested reasonable and commensurate with the proposed goals for Transition-to-Scale?
7. **Execution** – Can the proposed plan be feasibly implemented, sustained and financially supported during the Transition-to-Scale funding period and beyond?
8. **Compliance** – Will the proposed plan be compliant with relevant laws and regulatory regimes? Applicants must identify laws, regulations, national health plans, local health systems, and institutions that are relevant to the development, delivery, and uptake of funded innovations, and must indicate how they will comply and work within these rules and institutions.

Environmental Sustainability, Gender Equality, and Good Governance (EG2)

As outlined in Section 2.5, Grand Challenges Canada will evaluate Transition-to-Scale investment opportunities with input from external gender and environmental consultants, based on the following:

1. **Environmental Sustainability** – Does the proposal reflect Grand Challenges Canada's commitment to ensuring the prevention of material adverse environmental effects?
2. **Gender Equality** – Does the proposal reflect Grand Challenges Canada's commitment to furthering the principles of gender equality?

3. **Good Governance** – Does the proposal reflect Grand Challenges Canada’s commitment to furthering the promotion of good governance principles?

Global Access and Data Access

Grand Challenges Canada will also evaluate Transition-to-Scale investment opportunities based on the following:

1. **Intellectual Property** – Has the innovator obtained legal access to and/or managed intellectual property rights in a manner that enables the innovator to comply with Grand Challenges Canada’s Global Access Policy and Data Access Policy, and to provide rights to Grand Challenges Canada under a Global Access Agreement?
2. **Global Access** – Is the innovator’s Action Plan likely to lead to meaningful access to the innovation for target beneficiaries, particularly those among the marginalized and poor populations in LMICs?
3. **Data Access** – Does the innovator’s Action Plan contemplate publication and/or dissemination of results and data in an open, timely manner?

4.6 FINANCIAL TERMS

1. ELIGIBLE COSTS

The following costs directly related to the implementation of the Project are eligible:

Remuneration - Organization's Employees

Daily rates actually paid to employees for time actually worked on the implementation of the Project, based on a work day of seven and one-half (7.5) hours with a maximum of five (5) days per week. Timesheet system must be in use. Rates can include the following costs: direct salaries (excluding overtime pay and bonuses) and benefits in accordance with internal policies.

Fees - Subcontractors with an Arm’s Length Relationship with the Organization

The actual and justifiable cost of Subcontractors’ fees under a Sub-contract concluded with the Organization, where the Organization and the Subcontractor have an Arm’s Length Relationship. Individual rates or amounts negotiated shall not exceed the fair market value that applies to the specific type of service in the regular place of work of the Subcontractor or for similar work being performed under this Agreement and shall exclude any increased rate for overtime. The total subcontracting shall not exceed twenty percent (20%) of the total value of Grand Challenges Canada’s Contribution.

Reimbursable Costs

The actual and reasonable costs directly related to the implementation of the Project, such as:

1. Travel Costs, including the following travel costs incurred by the Organization in accordance:
 - The cost of commercial transportation based on the lowest available fares, using the most direct routing.
 - The cost of meals, incidentals and private vehicle usage.
 - The cost of registration, photographs, and courier services related to obtaining a visa.
 - The actual and reasonable cost of a single room in commercial accommodation.
 - All other actual and reasonable costs deemed legitimate Project expenses.
2. Recipient Country Government Employees: Costs (such as local transportation costs and living expenses while travelling) incurred by Government Employees of the Recipient Country who have been identified by the Recipient Country to work with Project Personnel for the purpose of the Project.
3. Goods and Supplies: Actual costs of publications and promotional materials directly related to the Project, such as business cards for Project personnel, posters and signage.
4. Project Administration Eligible Direct Costs related to the Project:
 - Long distance communications, including means of telecommunications (internet, fax, cellular), mail and courier costs;
 - Printing and production costs associated with Project reporting and production of reading material;
 - Meeting, workshops, and conference costs;
 - Legal fees: Legal costs directly related to sub-agreements;
 - Due diligence prior to signing a Sub-agreement;
 - Bank transfer fees.

Indirect/Overhead Costs

Indirect/Overhead Costs are not eligible under Grand Challenges Canada's agreements.

2. TERMS OF PAYMENTS

2.1 Advance Payments: An initial advance equal to the estimated cash flow requirements for Eligible Costs forecasted for the first period will be made upon signature of the Agreement. Subsequent payments will be made through quarterly advances based on the estimated cash flow requirements for Eligible Costs. Advances will be subject to a 5% holdback on the amount forecasted.

2.2 All advance requests and financial reports submitted shall be signed by a senior executive holding a certified professional accounting designation.

2.3 Outstanding Advances: Advance Payments cannot cover more than two periods and, at no time shall there be outstanding advances covering the cash flow requirements of more than two periods. For example, before an advance payment is issued for a third period, the first period must be accounted for.

2.4 Separate Bank Account and Interest Earned on Advance Payments: a separate bank account, bearing interest, shall be maintained for the project.

2.5 Final payment will be subject to the following conditions:

2.5.1.1 The Project is completed in accordance with the Agreement;

2.5.1.2 Grand Challenges Canada has received and accepted the Final Report; and

2.5.1.3 Grand Challenges Canada has received a certificate stating that financial obligations to Employees, Subcontractors or suppliers in respect of Grand Challenges Canada's Contribution to the Project have been fully discharged.

3. AUDIT

Audit: Project costs will be subject to audit by Grand Challenges Canada, up to three (3) years following the termination of the Agreement between Grand Challenges Canada and the fund recipient.

Proposals with thoughtful and efficient use of resources will be preferred over proposals representing comparable efforts that do not have the same value for the investment. In some circumstances (e.g. rapidly changing technologies), subcontracting specific project activities to an outside institution with the infrastructure and expertise to deliver results may be considered advantageous over establishing in-house capacity.

4.7 SUBMISSION MATERIALS AND PRIVACY NOTICE

To help us in the evaluation and analysis of projects, all proposals, documents, communications, and associated materials submitted to Grand Challenges Canada (collectively, "Submission Materials") may be shared with funding partners and other members of the Development Innovation Fund – Health Consortium (which includes, in addition to Grand Challenges Canada, the International Development Research Centre and Canadian Institutes of Health Research) with Global Affairs Canada, and/or with

other funding partners, and may be publicly disclosed. By submitting any Submission Materials to Grand Challenges Canada, each applicant thereby grants to Grand Challenges Canada and Her Majesty the Queen in right of Canada (“Her Majesty”) a worldwide, perpetual, irrevocable, non-exclusive, non-commercial, free of charge and royalty free license to use, reproduce, adapt, modify, improve, develop, translate, publish, disseminate, distribute, communicate to the public by telecommunication and display the Submission Materials, in whole or in part, in any form, media, or technology now known or later developed, including the right to authorize others to do such acts and the right to sublicense such rights to others, on the same terms. Each applicant also thereby waives any and all moral rights that it has in the Submission Materials in favour of Grand Challenges Canada, Her Majesty, and each of their sublicensees, successors, representatives, assigns, employees and agents.

The proposals will be subject to external review by independent subject-matter experts and potential co-funders (the results of which will be confidential), in addition to analysis by our staff.

Please carefully consider the information included in the Submission Materials. If you have any doubts about the wisdom of disclosure of confidential or proprietary information (including information related to inventions), we recommend you consult with your legal counsel and take any steps you deem necessary to protect your intellectual property. You may wish to consider whether such information is critical for evaluating the submission and whether more general, non-confidential information may be adequate as an alternative for these purposes.

We will attempt in good faith to respect the confidentiality of information we receive in Submission Materials, if it is clearly marked “Confidential”. Nonetheless, notwithstanding your characterization of any information as “Confidential”, we reserve the right to publicly disclose all information contained in Submission Materials as may be required by law, and as is necessary for potential co-funders and external reviewers (such as government entities) to evaluate them and the manner and scope of potential funding, consistent with appropriate regulations and their internal guidelines and policies. Grand Challenges Canada expressly disclaims any and all liability that may arise from disclosure of confidential information contained in Submission Materials.

4.8 WARRANTY

By providing any Submission Materials, applicants represent and warrant to Grand Challenges Canada that they have the right to provide the information submitted. Applicants with questions concerning the contents of their Submission Materials may contact Grand Challenges Canada by email at scaling@grandchallenges.ca.

4.9 INTELLECTUAL PROPERTY

The solutions supported by this program comprise innovative technologies, services, business models, knowledge and/or products to promote global health in LMICs. The successful development and deployment of these solutions in order to ensure meaningful

access for target beneficiaries in LMICs may require involvement by, support of, and/or collaboration with multiple organizations, including the private sector, government, and academic and/or non-profit research institutions. Accordingly, it is the intent of this program to support the formation of appropriate partnerships that are essential to meet these urgent global health needs. Successful applicants retain ownership of intellectual property rights in supported innovations, including those rights that arise in outputs of funded projects. Grand Challenges Canada aims, however, to ensure that any such intellectual property rights are utilized and managed in a manner that is consistent with achieving the goals of this program. Grand Challenges Canada's Global Access Policy will guide our approach to intellectual property, and we urge all applicants to consider their willingness to submit an application in compliance with Grand Challenges Canada's Global Access Policy, the guiding principles of which are as follows:

1. Breakthrough solutions to global challenges are made accessible to those in need, particularly in the developing world. Accessibility relates to both price and availability.
2. Knowledge gained through discovery is broadly, and as promptly as possible, distributed between related projects and to the global scientific community.
3. Commercialization of resulting outputs is encouraged, as long as the first two principles are achieved.

Successful applicants will be required to commit to compliance with the Grand Challenges Canada Global Access Policy; to develop an Access Plan for making their innovations meaningfully accessible to target beneficiaries in LMICs, meaning broadly and quickly available at costs that are reasonable in the context; and to sign a Global Access Agreement with Grand Challenges Canada, in line with the Guiding Principles, applicable to the innovative solutions and project outputs supported by this program. The Global Access Agreement will provide a non-exclusive license to intellectual property rights in supported innovations (including background intellectual property) and/or an agreement for distribution and supply of products, in each case permitting Grand Challenges Canada and its sub-licensees to implement and disseminate products, processes, knowledge, or solutions in low- and middle-income countries in which applicants or their partners are unable to achieve meaningful accessibility. Applicants should note that Grand Challenges Canada may be required to provide sub-license or sub-distribution rights to one or more persons appointed by Her Majesty, if Her Majesty reasonably determines that meaningful accessibility has not been achieved. Finally, upon request, applicants must agree to provide persons appointed by Her Majesty with a non-exclusive license to supported innovations to address an emergency situation that is subject to a declaration by the World Health Organization of a Public Health Emergency of International Concern.

Applicants should note that the above global access commitments survive the end of project activities.

4.10 DATA ACCESS

Grand Challenges Canada is committed to optimizing the use of data to translate knowledge into life-saving solutions. To fulfill this objective, data must be made available widely and rapidly to the Grand Challenges Canada community and the broader global health community through ethical and efficient data access practices. In accordance with global access, data access represents an elaboration of the second guiding principle of the Global Access Policy, which states that knowledge gained through discovery is broadly, and as promptly as possible, distributed between related projects and to the global scientific community.

Applicants will be required to develop and submit an Action Plan that specifies when and how findings and publications will be made openly accessible, how data access will be implemented, and the timeframe for data release.

At a minimum, ‘data’ refers to final, annotated quantitative and qualitative datasets, and accompanying information, such as metadata, codebooks, data dictionaries, questionnaires and protocols.

Grand Challenges Canada recognizes the value of intellectual property and commercialization, and the benefits of first and continuing use of data, but not prolonged or exclusive use. In some cases, intellectual property protection, laws or regulations may delay or preclude access to data. In cases where an adequate justification has been provided, Grand Challenges Canada may grant a partial or complete waiver of the data access requirement.

4.11 RIGHTS OF GRAND CHALLENGES CANADA

This Request for Proposals is part of a discretionary granting program. Submission of an application does not create a contractual relationship between the applicant and Grand Challenges Canada.

Furthermore, all applicants acknowledge that this program is being tested through this Request for Proposals and that all terms are subject to change. In particular, Grand Challenges Canada reserves the right, in its sole discretion and without notice, to:

1. Cancel this Request for Proposals at any time and for any reason.
2. Amend and reissue the Request for Proposals at any time and for any reason. This Request for Proposals is valid commencing on March 18, 2016, and supersedes any previous Request for Proposals of this nature. The terms and conditions of this Request for Proposals apply to all applications submitted from March 18, 2016, going forward and may be replaced by a revised Request for Proposals in the future. We recommend checking for any revisions to the Request for Proposals prior to the submission of your Letter of Intent or proposal.

3. Accept or reject any application that is non-conforming because it does not meet the eligibility criteria, does not comply with the application instructions and/or does not comply with the instructions for allowable costs.
4. Not award an application based on performance on a previous Grand Challenges Canada grant or project, or based on the award of a grant to the applicant for the same or similar research by one of Grand Challenges Canada's partners or collaborating institutions.
5. Disqualify any application at any stage where there is an indication that the proposal was, in any way, plagiarized.
6. Accept or reject any or all applications, regardless of an application's rating based on the evaluation criteria, with or without providing an explanation.
7. Award fewer awards than expected.
8. Award applications with different funding amounts, different durations and/or different conditions than set out above.
9. Verify any information provided by applicants through independent research or by contacting third parties deemed to be reliable by Grand Challenges Canada and use that information to inform Grand Challenges Canada's funding decision.
10. Modify eligibility and evaluation criteria, including but not limited to criteria assessed at the triage stage, at any time.
11. Use video or other visual representation submitted by applicants on Grand Challenges Canada's website for public engagement.
12. Not provide critiques or feedback regarding the reasons a proposal was or was not selected.
13. Design grant awards to link to possible funding partners, including private sector investors.

5. Research Assurances

It is the policy of Grand Challenges Canada that research involving human subjects, research with animals, and research subject to additional regulatory requirements must be conducted in accordance with the highest internationally-recognized ethical standards. In order to receive funds from Grand Challenges Canada, initially and throughout the course of a research project, researchers must affirm and document compliance with the guiding ethical principles and standards outlined below.

1. Research involving human participants must be conducted in a manner that demonstrates, protects and preserves respect for persons, concern for the welfare of individuals, families and communities, and justice.
2. Research involving animals must be conducted in a manner that ensures their humane care and treatment.
3. Certain research endeavours, including but not limited to research with recombinant DNA, biohazards and genetically modified organisms, may be subject to enhanced regulation and oversight.

While not necessary for this application and as applicable to the individual project, Grand Challenges Canada will require that, for each venue in which any part of the project is conducted (either by your organization or a sub-grantee or sub-contractor), all legal and regulatory approvals for the activities being conducted will be obtained in advance of commencing the regulated activity. We will further require you to agree that no funds will be expended to enroll human subjects until the necessary regulatory and ethical bodies' approvals are obtained. For further details, please see the Grand Challenges Canada Ethics policy at www.grandchallenges.ca/resources.

Questions about the Phase II – Transition to Scale program or the application process should be addressed to scaling@grandchallenges.ca. Responses to frequently asked questions will be periodically posted on our website at www.grandchallenges.ca.

Appendix A – Country Eligibility

Applicants from the following list of countries are eligible to apply to this Transition-to-Scale (Phase II) Request for Proposals. For the purposes of determining eligibility, Grand Challenges Canada may consider both the applicant’s home jurisdiction and any other jurisdiction within which project activities will take place. The list of countries is based on considerations such as the OECD DAC classification of low- and middle-income countries, other countries of strategic priority for Canada, and also includes Canada.

This list is subject to revision by Grand Challenges Canada without notice. Notwithstanding inclusion below, all eligible jurisdictions remain subject to approval by Grand Challenges Canada on the basis of compliance with all relevant Canadian and international laws and policies. Whenever possible, Grand Challenges Canada will provide reasonable notice of a determination of ineligibility for applicants located within jurisdictions listed below. Grand Challenges Canada reserves the right to invite applicants from countries not included in the list below, at its own discretion.



Effective for reporting on 2011, 2012 and 2013 flows.

| LEAST DEVELOPED COUNTRIES | OTHER LOW-INCOME COUNTRIES (per capita GNI <= USD 1 005 in 2010) | LOWER MIDDLE-INCOME COUNTRIES AND TERRITORIES (per capita GNI USD 1 006-3 975 in 2010) | UPPER MIDDLE-INCOME COUNTRIES AND TERRITORIES (per capita GNI USD 3 976-12 275 in 2010) |
|---------------------------|--|--|---|
| Afghanistan | Kenya | Armenia | Albania |
| Angola | Korea, Dem. Rep. | Belize | Algeria |
| Bangladesh | Kyrgyz Rep. | Bolivia | *Anguilla |
| Benin | South Sudan | Cameroon | Antigua and Barbuda |
| Bhutan | Tajikistan | Cape Verde | Argentina |
| Burkina Faso | Zimbabwe | Congo, Rep. | Azerbaijan |
| Burundi | | Côte d'Ivoire | Belarus |
| Cambodia | | Egypt | Bosnia and Herzegovina |
| Central African Rep. | | El Salvador | Botswana |
| Chad | | Fiji | Brazil |
| Comoros | | Georgia | Chile |
| Congo, Dem. Rep. | | Ghana | China |
| Djibouti | | Guatemala | Colombia |
| Equatorial Guinea | | Guyana | Cook Islands |
| Eritrea | | Honduras | Costa Rica |
| Ethiopia | | India | Cuba |
| Gambia | | Indonesia | Dominica |
| Guinea | | Iraq | Dominican Republic |
| Guinea-Bissau | | Kosovo ¹ | Ecuador |
| Haiti | | Marshall Islands | Former Yugoslav Republic of Macedonia |
| Kiribati | | Micronesia, Federated States | Gabon |
| Laos | | Moldova | Grenada |
| Lesotho | | Mongolia | Iran |
| Liberia | | Morocco | Jamaica |
| Madagascar | | Nicaragua | Jordan |
| Malawi | | Nigeria | Kazakhstan |
| Mali | | Pakistan | Lebanon |
| Mauritania | | Papua New Guinea | Libya |
| Mozambique | | Paraguay | Malaysia |
| Myanmar | | Philippines | Maldives |
| Nepal | | Sri Lanka | Mauritius |
| Niger | | Swaziland | Mexico |
| Rwanda | | Syria | Montenegro |
| Samoa | | *Tckelau | *Montserrat |
| São Tomé and Príncipe | | Tonga | Namibia |
| Senegal | | Turkmenistan | Nauru |
| Sierra Leone | | Ukraine | Niue |
| Solomon Islands | | Uzbekistan | Palau |
| Somalia | | Vietnam | Panama |
| Sudan | | West Bank and Gaza Strip | Peru |
| Tanzania | | | Serbia |
| Timor-Leste | | | Seychelles |
| Togo | | | South Africa |
| Tuvalu | | | *St. Helena |
| Uganda | | | St. Kitts-Nevis |
| Vanuatu | | | St. Lucia |
| Yemen | | | St. Vincent and Grenadines |
| Zambia | | | Suriname |
| | | | Thailand |
| | | | Tunisia |
| | | | Turkey |
| | | | Uruguay |
| | | | Venezuela |
| | | | *Wallis and Futuna |