

# REQUEST FOR PROPOSALS

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Grand Challenges Canada®  
Grands Défis Canada

**BOLD IDEAS WITH BIG IMPACT®**

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## **OPTions Initiative Request for Proposals**

Options for Pregnancy Termination Innovation Initiative, Round 1

November, 2018

## Executive Summary

"Women's rights are human rights. This includes sexual and reproductive rights — and the right to access safe and legal abortions. "

- Canada's ***Feminist International Assistance Policy***

Every year, there are more than 25 million unsafe abortions, resulting in approximately 7 million women and girls being admitted to health facilities for complications and 22,800 to 31,000 deaths. Virtually all (97%) of these unsafe abortions occur in developing countries<sup>1</sup>, where the greatest burden of death and disability is borne by the poorest of the poor.

Access to safe abortion is fundamental to gender equality and the empowerment of women and girls. The right to choose when and if to have a child affects women's and girls' ability to pursue education, build livelihoods, participate in society, and thrive. Limiting these abilities has a myriad of implications for the wellbeing of women, girls, their families and entire communities. And yet, even where abortion is legal and technically available, access to services is often limited due to a wide range of barriers, and there is often limited choice in terms of the method of abortion. Women and girls who choose to terminate a pregnancy often face significant stigma stemming from social norms and cultural beliefs, which is made worse by a lack of user-friendly and youth-friendly services.

Innovation is needed to overcome persistent barriers that continue to limit where, when and how a women or girl can terminate a pregnancy.

Access to safe and legal abortion is vital for the achievement of Sustainable Development Goal (SDG) 3: **Ensure healthy lives and promote well-being for all at all ages**, and SDG 5: **Achieve gender equality and empower all women and girls**, specifically for the targets of ensuring universal access to sexual and reproductive health and reproductive rights and reducing the global maternal mortality ratio.

The goal of the **Options for Pregnancy Termination Innovation Initiative (OPTions Initiative)** is to support **Bold Ideas with Big Impact®** for women's and girls' access to safe abortion in low- and middle-income countries. We seek innovative and transformative approaches that put women and girls in control of where, when and how they terminate their pregnancy. The focus of this call is therefore to support the development and testing of: 1) **new approaches to increasing early access to existing abortion products and services**, and 2) **new methods of pregnancy termination**.

Successful proposals will be awarded seed grants of up to \$250,000 CAD over 18 to 24 months to develop and test the proposed innovation. Assuming a sufficient number

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<sup>1</sup> Guttmacher Institute, *Abortion Worldwide 2017: Uneven Progress and Unequal Access* (March 2018)

of proposals of merit are received, Grand Challenges Canada aims to award approximately 20 seed grants this round.

By the end of the seed grant, innovators are expected to have demonstrated proof of concept of their idea, developed a plan for scale and sustainability, and attracted interest from key stakeholders and partners needed to proceed along a path to scale and sustainability. Successful innovators may be invited to apply for Transition to Scale funding.

**APPLICATION DEADLINE: February 12, 2019, at 3:00 P.M. ET**

**Due to processing times, we suggest registering for an account on the Fluxx Portal no later than February 5, 2019.**

**To apply for funding, applicants MUST use the online application form provided, which is ONLY accessible via the Grand Challenges Canada's Fluxx Portal ([gcc.fluxx.io](http://gcc.fluxx.io)). (Please see Section 4.2 *Application Instructions*)**

**For questions related to this Request for Proposals that are not addressed in the FAQ, contact [info@optionsinitiative.org](mailto:info@optionsinitiative.org).**

**If you require technical assistance with registration or the online application, contact Grand Challenges Canada's Fluxx Technical Support Team at <http://www.grandchallenges.ca/fluxxsupport/>**

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## 1. INTRODUCTION

### 1.1 GRAND CHALLENGES CANADA

Grand Challenges Canada's vision is: **A world in which innovation accelerates the achievement of Sustainable Development Goals.** Our mission is: **To catalyze innovation that saves and improves the lives of the most vulnerable in Canada and low- and middle-income countries.**

Grand Challenges Canada is dedicated to supporting Bold Ideas with Big Impact®. Funded by the Government of Canada and other partners, Grand Challenges Canada funds innovators in low- and middle-income countries and Canada. The bold ideas Grand Challenges Canada supports integrate science and technology, social and business innovation – known as Integrated Innovation®.

One of the largest impact-first investors in Canada, and with a feminist investment approach, Grand Challenges Canada has supported a pipeline of over 1000 innovations in more than 80 countries. Grand Challenges Canada estimates that these innovations have the potential to save up to 1 million lives and improve up to 28 million lives by 2030.

### 1.2 THE PROBLEM

The impact of unsafe abortion is profound. The Guttmacher Institute estimates that there are more than 25 million unsafe abortions annually. The vast majority of these abortions (about 97%) occur in the developing world. As a result, approximately 7 million women and girls are admitted to health facilities with complications and 22,800 to 31,000 women and girls die annually, making unsafe abortions one of the leading global causes of maternal mortality. Women in Africa are disproportionately affected, with 141 deaths per 100,000 induced abortions, compared to the case fatality rate of 62 deaths per 100,000 induced abortions in Asia, which is roughly equal to the global average.<sup>2</sup>

Voluntary family planning, including access to safe and legal abortion, has been shown to improve maternal and newborn health outcomes, advance women's empowerment, and bring socioeconomic benefits. Healthier women with fewer children participate more in the workforce, resulting in economic benefits that extend to children who are better educated and able to be more economically productive, thus leading to a reduction in poverty. When children are healthier, the average number of desired children decreases, bolstering a virtuous cycle for continuing improvements in health and economic development and further reductions in poverty.

Limiting these choices has a myriad of implications for the wellbeing of women, girls, their families and entire communities. And yet, even where abortion is legal and technically available, access to services is often limited due to a wide range of barriers, and there is often limited choice in terms of the method of abortion. For example,

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<sup>2</sup> Guttmacher Institute, *Abortion Worldwide 2017: Uneven Progress and Unequal Access* (March 2018)

abortion services often entail exorbitant costs and require prohibitively long-distance travel for multiple visits to a facility. Women and girls who choose to terminate a pregnancy often face significant stigma stemming from social norms and cultural beliefs, which is exacerbated by a lack of user-friendly and youth-friendly services, if they are able to access services at all.

These barriers not only delay women's access to safe abortion services, they also collectively contribute to the staggering number of deaths and disabilities seen annually as a result of unsafe abortion, which are disproportionately felt by the poorest of the poor in developing countries.

Innovation is needed to overcome persistent barriers that continue to limit where, when and how a women or girl can terminate a pregnancy.

## 2. APPROACH

### 2.1 THE OPTIONS INITIATIVE

The ultimate goal of the OPTions Initiative is to save and improve the lives of women and girls through improved access to safe and legal abortion.

The goal of this **Request for Proposals (RFP)** is to support **Bold Ideas with Big Impact**® for women's and girls' access to safe abortion in low- and middle-income countries. We seek innovative and transformative approaches that put women and girls in control of where, when and how they terminate their pregnancy. The focus of this call is therefore to support the development and testing of: 1) **new approaches to increasing early access to existing abortion products and services**, and 2) **new methods<sup>3</sup> of pregnancy termination**.

### 2.2 AREAS OF FOCUS

Grand Challenges Canada seeks bold ideas designed to be implemented in low- and middle-income countries that focus on **access to safe abortion**. These bold ideas could originate from non-profit organizations and for-profit organizations, as well as other recognized institutions. Social enterprises and feminist organizations are particularly encouraged to apply.

Proposed innovations must be **bold, innovative, transformational and 'outside-the-box'**, and must have the potential to make a substantial impact to improve access to safe abortion. The innovations are expected to improve access to safe abortion through either:

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<sup>3</sup> New methods are any methods other than the existing methods of safe abortion: manual vacuum aspiration (MVA) and medical abortion (MA).

1. **Increasing early access to manual vacuum aspiration (MVA)<sup>4</sup> and medical abortion (MA)<sup>5</sup>.** This includes but is not limited to the following:
  - a. Increasing the number of trained providers and available safe services
  - b. Improving access to information that will help a girl or woman safely terminate a pregnancy
  - c. Reframing and normalizing abortion to combat stigma
  - d. Decentralizing and de-medicalizing abortion care
  - e. Reducing economic barriers to accessing safe abortion
  
2. **Introducing a new method of safe abortion** that provides one or more significant improvements over existing methods, including:
  - a. When in gestation it can be effectively administered
  - b. Effectiveness at terminating pregnancy
  - c. Ability for girls and women to access and self-administer with greater autonomy and privacy
  - d. Ease of compliance (e.g. single pill administration)
  - e. Reduced side effects and pain
  - f. Stability profile
  - g. Permissive within existing regulatory frameworks (e.g., it has other primary indications)
  - h. Cost effectiveness

Please note that this is the target product profile for new methods of safe abortion. Both pre-clinical and clinical stage proposals are eligible, and project objectives for the 18 to 24 month grant period will be tailored accordingly.

### **2.3 TARGET BENEFICIARIES**

Innovations must ultimately benefit women and girls amongst the poorest of the poor in eligible low- and middle-income countries (Appendix A).

### **2.4 ABORTION WHERE LEGAL**

The focus of this call for proposals will be on addressing barriers that limit access to safe abortion in countries where there are one or more legal grounds to support it<sup>6</sup>. While

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<sup>4</sup> Manual Vacuum Aspiration (MVA) is a surgical method of abortion that removes pregnancy tissue from the uterus.

<sup>5</sup> Medical Abortion (MA) uses Mifepristone and Misoprostol pills to induce abortion.

<sup>6</sup> Guttmacher Institute, *Abortion Worldwide 2017: Uneven Progress and Unequal Access* (March 2018), Appendix Table 1 (pg. 50). The abortion legality continuum ranges from category 1, outright prohibition on any ground, to category 6, allowing abortion without restriction as to reason. The four intermediate categories permit abortion on progressively broader grounds: to save a woman's life, to protect a woman's physical health, to protect her mental health, and for socioeconomic reasons. Many countries permit abortion on at

prohibitive laws and policies are recognized as a key determinant to the uptake of safe abortion services, legal reform is not an objective of this call. The OPTions Initiative also intends to increase awareness and understanding of local laws to ensure women know their rights. Innovators must have a strong plan in place to mitigate risks of unintended negative consequences that could stem from increased awareness of safe abortion rights and services, such as the risk of more restrictive policies being implemented.

## **2.5 WHAT GRAND CHALLENGES CANADA WILL NOT FUND**

Grand Challenges Canada will not consider funding capacity-building initiatives, ongoing programmatic funding, ideas that are not applicable to poor women and girls in low- and middle-income countries, and ideas that are not transformative, innovative, and do not push the field beyond current paradigms and assumptions.

Grand Challenges Canada will not consider funding projects that involve establishing proof-of-concept of innovations for which the core intellectual property rights are owned by a third party institution, unless either (a) the third party institution has granted the applicant sufficient license rights to the innovation to permit eventual scaling in low- and middle-income countries, or (b) the third party institution is willing to sign an undertaking to Grand Challenges Canada committing to comply with Grand Challenges Canada's Global Access requirements.

Grand Challenges Canada will not consider funding innovations that are similar to innovations previously funded by Grand Challenges Canada. See our website for a searchable database of innovations funded by Grand Challenges Canada (<http://www.grandchallenges.ca/who-we-are/discover-our-innovations-and-results/>).

## **2.6 AVAILABLE FUNDING**

Successful proposals will be awarded seed grants of up to \$250,000 CAD over 18 to 24 months to develop and test the proposed innovation. Assuming a sufficient number of proposals of merit are received, approximately 20 seed grants will be awarded in this round.

### **Transition to Scale Funding**

A limited number of innovations funded through this RFP may have the opportunity to apply for transition-to-scale funding of up to \$1,000,000 CAD, if funding is available, to support the refinement, testing and implementation for scale of innovative solutions that have already achieved proof of concept. Transition-to-scale projects are expected to demonstrate large-scale, real-world impact on access to safe abortion and move towards scale and sustainability. Transition-to-scale projects require support from partners who bring both matching funds and the necessary skill sets to the innovations to operate sustainably at scale. Please visit <http://www.grandchallenges.ca/programs/transition-to-scale/> for further information on transition to scale funding.

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least one of the following three additional grounds: if the pregnancy resulted from rape or incest, or if the fetus has a grave anomaly.



While matching funds are not a requirement at the seed funding stage, all innovators are encouraged to secure co-funding. Initiating early strategic partnerships can improve the sustainability of an innovation by creating early buy-in, and providing resources and expertise that may prepare teams for the transition to scale process, which requires matching funds through partnerships.

**Please note:** All successful applicants must complete their project within 24 months. No-cost extensions will not be provided and exceptions are at Grand Challenges Canada's sole discretion.

## 2.7 FOCUS ON RESULTS

The ultimate outcomes of interest for the OPTions Initiative are **lives of women and girls saved and improved**. Funded projects are expected to demonstrate impact on the health and rights of women and girls in eligible low- and middle-income countries. To this end, projects should have a monitoring and evaluation approach to clearly measure these outcomes, identify shortcomings and maximize impact. In the case where it is not feasible to measure lives saved and/or improved during seed funding, projects are expected to demonstrate measurable change in at least one of the following outcomes:

- Improved access to existing methods of safe abortion
- Reduced delays in a woman's decision to seek care, reach a facility, and/or receive care
- Scientific evidence of a new drug, formulation, or prototype for pregnancy termination that is a significant improvement over existing methods.

Innovators are expected to report against any indicators listed in Appendix B that are relevant to demonstrating success of their innovation.

Success for seed grants is defined as:

- Evidence from a controlled or limited setting that the innovation improves access to safe abortion and/or reduces significant barrier(s) to accessing safe abortion
- Evidence that the innovation can be feasibly implemented, sustained and financially supported at scale in the target region(s)
- Demonstrated interest, financing and/or commitments for uptake of the innovation from key stakeholders, influencers and partners needed to enable scale and sustainability

### Communicating Results

Communicating results is also an important part of the project's accountability to the OPTions Initiative partners and other key stakeholders. Proposals should include a brief overview of how they plan to engage stakeholders and disseminate results, the different audiences they intend to reach, and how this dissemination will contribute to the innovation's impact, scale and sustainability. While communicating results through scientific publications is important, this should not be the primary objective of funded projects without a well-articulated justification that this is on the critical path to impact.

## 2.8 INTEGRATED INNOVATION

Projects are expected to take an Integrated Innovation<sup>®</sup> approach, defined as the coordinated application of scientific/technological, social and business innovation, to develop solutions to complex challenges. 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: <http://www.grandchallenges.ca/funding-opportunities/integrated-innovation/>.

Proposed solutions should therefore include a combination of:

- **Scientific/Technological Innovation:** Has a base in the psychological, natural, health or behavioural sciences or in engineering or economics; can be simple, i.e. there is no requirement for high-tech solutions
- **Social Innovation:** Recognizes and/or addresses the broader social, structural and/or political determinants of health, with a particular focus on gender and intersectional inequalities; addresses local and/or cultural contexts that factor into implementation and scaling
- **Business Innovation:** Maximizes the value, relevance and unique quality of the solution to create demand and financial sustainability; addresses barriers to affordability and accessibility

## 2.9 SCALE AND SUSTAINABILITY

Grand Challenges Canada expects that the most successful innovations it funds will eventually be scaled up through partnerships – either with the private sector, the public sector or a combination of both – and that such scaling will be carried out with the goal of achieving meaningful health impact for the poorest of the poor in low- and middle-income countries. Applicants should convincingly show in their application how and why they believe their projects will eventually be scaled by one or both of the following pathways:

- Private sector scaling paths are suitable for projects that are commercially viable or provide value to attract a private sector partner, either because production costs and sales prices are such that they are profitable, or beneficiaries demand the innovation and are willing to pay for it themselves.
- Public sector scaling paths are suitable for projects that are likely to compel host country government ministries and departments, multilateral donors or other public sector players to scale them. These should be aligned to, and have the ability to be incorporated into, the country's national health plan or strategy.

Seed funding should enable innovations to position themselves along a clearer path to scale, taking into account the following factors: the state of local infrastructure; social, political, and economic forces; the capacity of the institution and its leadership; potential strategic and implementation partners; available funding and revenue streams; and other

potential barriers to scale. Projects are recommended to leverage local systems where this will lead to efficiencies and to meaningful engagement with the women and girls who are meant to benefit to increase the likelihood of scale-up. This should include an understanding of: how the innovation relates to local priorities (e.g. national/regional health plans); why the innovation would be preferred over alternatives; and push/pull mechanisms supporting market formation and consumer demand. The plan should clearly define the geography or context of use at scale, as well as exit strategies from grant funding.

### **Social Entrepreneurship**

Social entrepreneurs are strongly encouraged to apply to this RFP. Social entrepreneurs are individuals with innovative solutions to society's most pressing social problems. They are ambitious and persistent, tackling major social issues by offering new ideas for wide-scale change. Whereas business entrepreneurs typically measure performance in profits, social entrepreneurs seek a sustainable approach to achieve social returns to society. Grand Challenges Canada believes social entrepreneurship is a critical feature to enable scaling, sustainability and the ultimate achievement of impact.

### **Understanding Local Context**

To help ensure sustainable impact at scale, it is essential that project teams include member(s) with an understanding of the local infrastructure and governance context (including relevant laws and regulations) and the social, political and economic context. In doing so, projects can better address the health status and needs of the community, and identify risks to project success. Where they exist, innovations should build upon local systems that are able to reach the target population that support health and/or development, or address broader determinants of health. Determinants of health include: poverty, inequality (including gender inequality), and access to water and sanitation resources. Innovations should be relevant to low-resource settings, and benefits of these innovations should target poor, marginalized populations of low- or middle-income countries.

Access to safe abortion is influenced by multiple factors, including but not limited to: household power dynamics and gender equality broadly; financial access to services; legal frameworks; social norms and stigma; cultural and religious beliefs; availability of other sexual and reproductive health and rights services; and regional, national and global political environments. As a result, it is anticipated that families, communities, healthcare providers, businesses, policy-makers, governments and international agencies can all play a role in guiding and supporting the project.

### **Stakeholder Engagement**

Stakeholders, especially the women and girls who will ultimately make decisions about using the proposed solution, should be engaged at the outset and throughout the life of the project. This will help to ensure that the solution will be poised for adoption. Additionally, stakeholders can offer insight into their community and identify the factors necessary for project success.

## 2.10 GENDER EQUALITY, ENVIRONMENTAL SUSTAINABILITY, AND HUMAN RIGHTS AND INCLUSION

Grand Challenges Canada is committed to furthering the principles of gender equality, environmental sustainability, and human rights and inclusion. As such, innovators are required to comply with Grand Challenges Canada Policy on [Gender Equality, Environmental Sustainability and Human Rights and Inclusion](#) as follows:

1. **Gender Equality:** Grand Challenges Canada believes that supporting gender equality and the rights of women and girls is an important objective in and of itself, as well as a critical development objective, and therefore aims to contribute to achievement of equality between persons of all genders (see the Gender Equality Portal at <http://www.grandchallenges.ca/funding-opportunities/gender/> for a set of gender equality tools). Grand Challenges Canada's baseline is to do no harm. Innovators funded or under review for funding by Grand Challenges Canada must consider how the design, implementation and evaluation of their innovation could promote – or hinder – gender equality objectives, and must take actions towards realizing gender equality opportunities within the funding period. In addition, Grand Challenges Canada is committed to advance gender equality in the leadership and governance of innovation, and to that end, strives to source and promote support systems to ensure equal access to progressive levels of financing for all genders and diversity in governance structures. Gender equality objectives include, but are not limited to:
  - i. Advance women's equal participation and support women and girls in the realization of their full human rights: Grand Challenges Canada seeks to support processes and innovations that actively engage and empower women and their communities to further women's equal participation and status in their societies.
  - ii. Reduce gender inequalities around the access to and control over the resources and benefits of development: Innovators should strive to understand and mitigate gender gaps in the contexts in which they operate, to work towards the achievement of gender equality and other, broader goals of development.
2. **Environmental Sustainability:** Grand Challenges Canada is, in part, funded by the Government of Canada through Global Affairs Canada and aligns with its efforts in supporting environmental sustainability in developing countries, and the Canadian Environmental Assessment Act (CEAA) 2012. The reasonably foreseeable environmental impacts of innovations funded or under review for funding by Grand Challenges Canada must be considered at the planning stage and, where applicable, monitored and evaluated throughout implementation. Efforts should be made to identify and minimize negative impacts and enhance positive impacts, if any, on the environment(s) in which the innovation is deployed.

- 3. Human Rights and Inclusion:** Grand Challenges Canada is committed to furthering the integration of, and enabling conditions for, promoting the human rights principles of equality, non-discrimination, participation, inclusion, transparency, and accountability from proposal development through implementation. Grand Challenges Canada works with innovators to strengthen their focus on these key human rights principles in the design of the innovation(s) and in the systems and processes used in the implementation of the innovation(s) in the specific context in which they are working. More specifically, innovators who have submitted a proposal or are implementing an innovation must consider how the innovation will, at a minimum, 'do no harm' with respect to the human rights of project stakeholders and beneficiaries. In the design and implementation of the innovation(s), the innovator must take into consideration how the innovation will:
1. Identify ways in which the innovation can support poverty reduction in the local population, particularly for women and girls;
  2. Ensure equality and non-discrimination, including on the basis of gender, for project stakeholders and beneficiaries;
  3. Foster the participation and inclusion of more marginalized stakeholders and beneficiaries among the local population, with an emphasis on women and girls; and
  4. Promote transparency and accountability among stakeholders and beneficiaries of the innovation and its intended impact.

## 2.11 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 can 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 are disseminated broadly and promptly to the global research community and beyond; (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 is 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 are appropriately considered in all data access activities; (3) collection, production, sharing and use of data are 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; (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.

Innovators are required to: (1) commit to compliance with the above policies; (2) ensure that intellectual property rights, including those of third parties, do not impede meaningful access to innovations and widespread dissemination of knowledge; (3) grant Grand Challenges Canada a limited, non-exclusive license to intellectual property rights in their innovations, applicable only in the event of an inability to secure meaningful access for target beneficiaries in low- and middle-income countries or in the context of a World Health Organization-declared Public Health Emergency of International Concern.

### 3. ACTIVITIES AND DELIVERABLES

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

1. Performance reporting focused on utilization of funds and outcomes achieved. The frequency of reporting will be every three or six months, depending on our assessment of project and institutional risk.
2. Dissemination of knowledge in a timely manner, including through social media, open access publications, depositing of data into publicly accessible repositories, press releases, conferences, stakeholder engagement, etc. Acknowledgement of Grand Challenges Canada will be required. **Please note** that innovators will be expected to publish their findings in open access journals or through open access publishing platforms, typically within 12 months of completing their seed grant.
3. A final report that accounts for financial expenditures and that captures a clear assessment of the impact of the project. Please note that a 5% hold back of funds will be applied to all funding under this program, to be released to innovators upon submission of a satisfactory final report and full justification of costs.

3. Continued post-grant updates on impact, global access, data access and management of intellectual property rights in supported innovations.

Instructions for reporting will be provided to successful recipients. Written progress reports and conversations via teleconference may be required to satisfy reporting requirements. In addition to the above-mentioned activities, innovators will be expected to:

1. Participate in public engagement activities, to the extent that their safety is not put at risk.
2. Contribute to the learning agenda for specific challenges, including through participation in meetings, such as the annual Grand Challenges meetings.

Funded innovators must retain supporting project documentation, including financial records, and may be audited by Grand Challenges Canada or any funders of this initiative, at any time up until March 31, 2025; associated requirements will be reflected in funding agreements.

## **4. RULES AND GUIDELINES**

Submitted proposals go through a multi-step review process before Grand Challenges Canada makes a recommendation for funding. Grand Challenges Canada's Board of Directors makes the final funding decisions. For more details: [grandchallenges.ca/our-people](https://grandchallenges.ca/our-people).

### **4.1 ELIGIBILITY CRITERIA**

1. Eligible applicants include social enterprises and other recognized institutions (e.g., non-profit organizations, academic institutions, and for-profit companies) that are formed and legally incorporated, that can successfully execute the activities in their respective technical area, and that are capable of receiving and administering grant funding. Sole proprietorships are not eligible for funding. United Nations country offices are not eligible to apply.
2. A project can have only one (1) Project Lead, who must be affiliated with the institution from which the proposal is being submitted.
3. A Project Lead may only be listed on one (1) application to this Request for Proposals; however, an institution may submit multiple applications. For multiple applications to be considered from a single institution, the applications must each list a different Project Lead. Please note: each Project Lead must register for their own unique Fluxx Portal account.
4. Applications must include all required information. Only complete applications will be considered by the Review Committee.

5. Proposed ideas must be aligned with the Areas of Focus (Section 2.2) and the Target Beneficiaries (Section 2.3). Anything that falls under What Grand Challenges Canada Will Not Fund (Section 2.5) is not eligible.
6. It is the applicant's responsibility to obtain any necessary legal and/or regulatory approvals, consents or reviews required to accept foreign grant funds and/or conduct the project activities before executing a funding agreement with Grand Challenges Canada. For example, applicants planning to conduct project activities in India may be required to register with the Ministry of Home Affairs under the Foreign Contribution Regulation Act of 2010 (FCRA). As part of the Grand Challenges Canada's diligence, successful applicants will be required to provide their organization's registration under FCRA or a written certification that FCRA registration is not required. Failure to comply with the requirements of FCRA may subject your organization to financial and/or criminal penalties. You should consult with your own advisors to determine whether FCRA applies to your organization or project.
7. Grand Challenges Canada may, at any time and at their sole discretion, modify eligibility criteria with respect to individual applicants, Project Leads and/or eligible countries, to the extent that such modifications do not materially undermine the review process.

**Please note** that Grand Challenges Canada must approve any changes in applicant organization, institution or Project Lead from the originally-submitted application.

**Please note** that collaboration with an innovator based in a low- or middle-income is encouraged for applicants from high-income countries, but it is not required.

**Please note** that Project Leads are required to seek and obtain sign-off from their affiliated institution before submitting their application.

## 4.2 APPLICATION INSTRUCTIONS

**To apply for funding, applicants MUST use the online application provided, which is ONLY accessible via the Grand Challenges Canada's Fluxx Portal ([gcc.fluxx.io](https://gcc.fluxx.io)).**

1. Go to <https://gcc.fluxx.io>.
  - If you have applied for funding in the past, you **already** have an account. If you do not remember your password, you can reset it and gain immediate access to the Portal, simply click on the **Create or reset password** link.
  - If you are a brand new user (or the "forgot password" option does not work), you must click the **Create an account** button.

Please note: If registering for a new account on behalf of a colleague, you must enter all information (including the date of birth) of the applying Project Lead and the applying



Organization. These names will display on the application form and cannot be changed without contacting an Administrator.

2. *For new accounts only* – It will take one (1) business day to receive your login credentials, and may take longer during peak periods. Therefore, we suggest requesting an account no later than February 5, 2019. Once your information has been processed, you will be emailed a username and a URL to set up a password of your choice. Click on the URL provided in the email to select a password of your choice.
3. Input your username and password. Click **Sign in**.
4. Click on the Welcome/Bienvenue link on the left menu, scroll down click on the **Start an Application** button.
  - Google Chrome is the recommended browser (DO NOT use Internet Explorer).
  - You can **Save** your work at any time and return to it later by logging into your account and clicking on **Drafts / Ébauches**, then clicking on **Edit**.
  - When you are done editing, save your form and click the **Submit** button. Once you submit, you will no longer be able to edit, so please take care when completing the form.
  - You **MUST** complete your application by clicking the **Submit** button within the application form by **February 12, 2019, at 3:00 P.M. ET**.

For more details on the steps above (including screen shots) please see the [FLUXX QUICK REFERENCE GUIDE](#) which describes how to create a Fluxx Portal account, how to reset the password on an existing account and other helpful tips on navigating Fluxx and the application form.

Both new and returning Portal users should read the **Fluxx Quick Reference Guide** linked above to avoid any technical issues. If you require technical assistance with registration or the online application, contact Grand Challenges Canada's Fluxx Technical Support Team at <http://www.grandchallenges.ca/fluxxsupport/>.

The application can be submitted in either English or French. Applications in other languages will not be considered. To change the language of your application, go to the **Edit Profile** link on the left menu.

Please note: Any application sent via email will not be considered.

Please note: Grand Challenges Canada cannot provide application questions via email. The application form is only visible on [gcc.fluxx.io](http://gcc.fluxx.io). You must register for an account using the instructions above.

### **Innovator Toolbox**

Applicants are encouraged to access Grand Challenge Canada's online Innovator Toolbox at [grandchallenges.ca/innovator-toolbox](http://grandchallenges.ca/innovator-toolbox), which contains materials to help

researchers and innovators to develop their project proposals and to plan for how their innovation will go to scale, be sustained and have global impact. Also see the Gender Equality Portal at <http://www.grandchallenges.ca/funding-opportunities/gender/> for a set of gender equality tools.

#### 4.3 APPLICATION TIMELINE

Key Dates	Event
February 5, 2019	<p><b>Suggested deadline to <a href="http://gcc.fluxx.io">register for a Fluxx account</a> (gcc.fluxx.io)</b></p> <p>Note: If you have applied for funding in the past, you <b>already</b> have an account. If you do not remember your password, you can reset it and gain immediate access to the Portal, simply click on <b><a href="#">Create or reset password</a></b>.</p>
February 12, 2019	<b>Application deadline at 3:00 p.m. ET</b>
September 30, 2019	<b>Notification of application status</b>
December 31, 2019	<b>Anticipated start date of projects</b>

#### 4.4 REVIEW PROCESS

An independent scientific peer review process for this initiative, which includes an Eligibility Screen and Innovation Screen conducted by Grand Challenges Canada, will be conducted.

##### **Eligibility Screen**

Grand Challenges Canada will screen applications on the basis of the eligibility criteria outlined in Section 4.1. Applications that do not meet the eligibility criteria will be removed from the competition.

##### **Innovation Screen**

Applications will be internally scored for strategic relevance to this Request for Proposals. The innovation screen will evaluate only the proposed innovative idea (not the feasibility or quality of the project plan) for novelty and potential to contribute uniquely to

the OPTions Initiative. Proposals that lack innovation and relevance will be removed from the competition at this stage. We will not consider projects that are similar to projects we have already funded. See our [website](#) for a searchable database of innovations funded by Grand Challenges Canada.

Applications will be scored against the criteria below using the **Project Summary paragraphs** only, as indicated on the application. The two criteria below are equally weighted:

### 1. Innovation

- Is the proposed solution aimed at increasing access to safe abortion in low- and middle-income countries innovative and clearly articulated?
- Does the innovation represent more than an incremental improvement over current approaches?
- Is a coordinated application of integrated scientific/technological, social and business innovation clearly demonstrated, as defined in Section 2.6?

### 2. Relevance

- Does the proposed solution address the specific problem described in Section 1.2 and the OPTions Initiative as described in Sections 2.1 and 2.2?
- Does it apply to poor, marginalized populations in low- or middle-income countries and aim to address gender inequalities?

### Peer Review

An independent scientific peer review process for this initiative, which includes an Eligibility Screen and Innovation Screen conducted by Grand Challenges Canada, will be conducted. A review committee of external scientific, social and business reviewers, including experts from low- and middle-income countries, will advise on the merit of proposals and rate each application based on the evaluation criteria in Section 4.5.

## 4.5 EVALUATION CRITERIA

### 1. Impact and Potential for Transformation

- How transformative is the proposed innovation on access to safe abortion in low- and middle-income countries?
- How well does the proposal address the key barriers that limit access to safe abortion?
- How appropriate is the proposed innovation for wider implementation and scaling in low- and middle-income countries?
- Does the innovation have the potential to address inequalities, be feasibly implemented, sustained and financially supported in the target region (taking into account the state of the local infrastructure; governance context (including relevant laws and regulations); social, political and economic forces; the capacity of the institution and its leadership; potential strategic and implementation partners; available funding and revenue streams; and other potential barriers to scale)?

## 2. Integrated Innovation

- How bold, novel and/or how much of a departure from incremental improvements is the innovation over current approaches?
- How clearly does the plan identify the barriers to scale and sustainability?
- How well does the proposed idea integrate scientific/technological, social and business innovation?
- Are key stakeholders, especially the women and girls of the target population, meaningfully engaged in the design and testing of the proposed project?

## 3. Project Execution Plan

- Is the project designed to demonstrate proof of concept of the idea?
  - Will the project provide on-the-ground evidence of the impact on access to safe abortion *and* on how the innovation may be feasibly implemented, sustained and financially supported in the target region?
  - Will the project provide scientific evidence of a new drug, formulation, or prototype for pregnancy termination that is a significant improvement over existing methods?
- How well articulated, feasible and technically sound is the execution plan?
- Are the timelines proposed appropriate and feasible?
- How appropriate, feasible and technically sound is the monitoring and evaluation plan, including gender equality results?
- How appropriate are the metrics to evaluate progress toward achieving proof of concept?
- How well does the proposal take into account and aim to address Grand Challenges Canada's gender equality, environmental sustainability and human rights and inclusion objectives?
- Is there a feasible plan to identify and apply learning for improved outcomes as the project unfolds?
- Is there evidence provided to indicate the likelihood of success, and a rigorous assessment of risks and associated mitigation strategies?

## 4. Leadership Capability to Champion Change

- Does the Project Lead have the commitment and leadership potential needed to bring solutions to scale?
- Are the proposed Project Lead and key team members appropriately trained, experienced and positioned to carry out the proposed work (i.e., scientific, social and business expertise)?
- Do the proposed partnerships and composition of multi-disciplinary teams increase the likelihood of success?
- Have the Project Lead and key team members demonstrated the ability to convene necessary stakeholders who can influence systems change (e.g., business, academic and public sectors), including those new to the project and its goals?

## 5. Value for Effort

- Are the scope of the proposed work and the funds requested reasonable and commensurate with the proposed proposal goals?
- Does the proposal represent a particularly thoughtful and efficient use of resources?

## Funding Decisions

Upon completion of the peer review, Grand Challenges Canada will receive a ranking list and ratings. Based on the results of the peer review, Grand Challenges Canada will make a funding recommendation to the Board of Directors of Grand Challenges Canada, which will make the final funding decisions at the Board's sole discretion, including its reserved rights set out in Section 4.13. Only projects rated as fundable during peer review may be recommended for funding. Due diligence, including the applicant's performance on other projects funded by Grand Challenges Canada and its partners, is taken into account for all projects recommended by peer review for funding. Based on the results of the review committee or due diligence process, refinements to the proposed project plan, structure, amount, type of funding and oversight may be required during the negotiation of a funding agreement.

## 4.6 FINANCIAL TERMS AND ELIGIBLE COSTS

Costs directly related to the implementation of the project are eligible as per the [Eligible & Ineligible Expenses Directive](#).

The following **indirect** cost rates are allowed:

- Up to 15% for non-profit and non-governmental organizations
- Up to 10% for universities
- 0% for governmental bodies and for-profit agencies

If an organization's published or audited indirect rate is less than the maximum allowable indirect rate above, the grantee should apply its published or audited rate for proposal budgeting purposes. Additionally, indirect-cost rates **cannot** be applied to equipment or supply purchases, including depreciation.

Indirect cost rates also apply to approved sub-contractors that are part of the proposal. Indirect costs paid on approved sub-contracts are limited to the first \$25,000 of each sub-contract per year (12 months) of implementation. Indirect cost rates may not be applied to the following types of sub-contracted services: business supply services, administrative support services, audiovisual services, architect and engineer services, construction, or equipment maintenance. Sub-contractors may not charge the primary applicant for indirect cost rates that are in excess of the above stated policy.

## 4.7 TERMS OF PAYMENTS

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 or

semi-annual advances based on the estimated cash flow requirements for Eligible Costs. Advances will be subject to a 5% holdback on the amount forecasted.

2. All advance requests and financial reports submitted shall be signed by a senior executive holding a certified professional accounting designation.
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.
4. Separate Bank Account and Interest Earned on Advance Payments: A separate bank account, bearing interest, shall be maintained for the project.
5. Final payment (the holdback of up to 5% of the grant amount) will be subject to the following conditions:
  - a. The Project has been completed in accordance with the Agreement.
  - b. Grand Challenges Canada has received and accepted the final report.
  - c. Grand Challenges Canada has received a certificate stating that financial obligations to employees, subcontractors or suppliers with respect to Grand Challenges Canada's contribution to the Project have been fully discharged.

#### **4.8 AUDIT**

Funded innovators may be audited by Grand Challenges Canada or any of its partners, at any time up until March 31, 2025 and must retain project records during that period, all of which will be reflected in each funding agreement.

#### **4.9 SUBMISSION MATERIALS AND PRIVACY NOTICE**

All proposals, documents, communications, including videos and associated materials submitted to Grand Challenges Canada in response to this Request for Proposals (collectively, "Submission Materials") may be shared with any funding partners.

By submitting any Submission Materials to Grand Challenges Canada, each applicant thereby grants to Grand Challenges Canada 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.

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.

Grand Challenges Canada expressly disclaims any and all liability that may arise from disclosure of confidential information contained in Submission Materials.

#### **4.10 WARRANTY**

By providing any Submission Materials, applicants represent and warrant to Grand Challenges Canada that they have the right to provide the information submitted and to grant the above licenses. Applicants with questions concerning the contents of their Submission Materials may contact Grand Challenges Canada by email at [info@optionsinitiative.org](mailto:info@optionsinitiative.org).

#### **4.11 INTELLECTUAL PROPERTY**

The solutions supported by this program comprise innovative technologies, services, business models, knowledge and/or products to promote access to safe abortion in low- and middle-income countries. In order to ensure meaningful access for relevant populations, the successful development and deployment of these solutions 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.

Successful applicants will be required to commit to compliance with Grand Challenges Canada's Global Access Policy 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) permitting Grand Challenges Canada and its funding partners 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 the funding partners, or one or more persons appointed by the funding partners. Applicants should note that the above global access commitments survive the end of project activities.

#### **4.12 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 widely and rapidly available to Grand Challenges Canada's research 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.

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 such cases, the grantee will provide justification to warrant a partial or complete waiver of the data access requirement.

#### **4.13 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.

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 November 12, 2018, 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 November 12, 2018, 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 application.
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 ranking, based on the evaluation criteria, with or without providing an explanation.
  7. Award applications with different funding amounts, different durations and/or different conditions than set out above.
  8. 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.
  9. Provide grants in collaboration with funding partners. This may involve separate grant agreements with each institution (i.e., one with Grand Challenges Canada and one with a partner institution), as well as distinct transfers of funds. Any such funding may be subject to terms and conditions beyond those described herein. The project deliverables, however, will be aligned.

#### **4.14 RESEARCH ASSURANCES**

As noted above in Section 2.10, 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.

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 institution or a sub-grantee or subcontractor), 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 Grand Challenges Canada's Ethics Policy (<https://www.grandchallenges.ca/wp-content/uploads/2017/10/20170927-EthicsPolicy-EN.pdf>).

## Appendix A: World Bank Low- and Middle-Income Country List

The World Bank classifies the following countries as low- and middle-income. **It is the responsibility of the applicant to ensure that they are in compliance with applicable laws.** For the most up to date list of low- and middle-income countries, please refer to: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>.

Low-Income Countries	Lower-Middle Income Countries	Upper-Middle Income Countries
Afghanistan	Angola	Albania
Benin	Bangladesh	Algeria
Burkina Faso	Bhutan	American Samoa
Burundi	Bolivia	Armenia
Central African Republic	Cabo Verde	Azerbaijan
Chad	Cambodia	Belarus
Comoros	Cameroon	Belize
Congo, Dem. Rep.	Congo, Rep.	Bosnia and Herzegovina
Eritrea	Côte d'Ivoire	Botswana
Ethiopia	Djibouti	Brazil
Gambia, The	Egypt, Arab Rep.	Bulgaria
Guinea	El Salvador	China
Guinea-Bissau	Georgia	Colombia
Haiti	Ghana	Costa Rica
Korea, Dem. People's Rep.	Honduras	Cuba
Liberia	India	Dominica
Madagascar	Indonesia	Dominican Republic
Malawi	Kenya	Equatorial Guinea
Mali	Kiribati	Ecuador
Mozambique	Kosovo	Fiji
Nepal	Kyrgyz Republic	Gabon
Niger	Lao PDR	Grenada
Rwanda	Lesotho	Guatemala
Senegal	Mauritania	Guyana
Sierra Leone	Micronesia, Fed. Sts.	Iran, Islamic Rep.
Somalia	Moldova	Iraq

South Sudan	Mongolia	Jamaica
Syrian Arab Republic	Morocco	Jordan
Tajikistan	Myanmar	Kazakhstan
Tanzania	Nicaragua	Lebanon
Togo	Nigeria	Libya
Uganda	Pakistan	Macedonia, FYR
Yemen, Rep.	Papua New Guinea	Malaysia
Zimbabwe	Philippines	Maldives
	São Tomé and Príncipe	Marshall Islands
	Solomon Islands	Mauritius
	Sri Lanka	Mexico
	Sudan	Montenegro
	Swaziland	Namibia
	Timor-Leste	Nauru
	Tunisia	Paraguay
	Ukraine	Peru
	Uzbekistan	Romania
	Vanuatu	Russian Federation
	Vietnam	Samoa
	West Bank and Gaza	Serbia
	Zambia	South Africa
		St. Lucia
		St. Vincent and the Grenadines
		Suriname
		Thailand
		Tonga
		Turkey
		Turkmenistan
		Tuvalu
		Venezuela, RB

## Appendix B: Key Indicators

Outcomes	Potential Indicators
Improved access to safe abortion where legal	<p>Number of women and girls with enhanced access to safe and legal abortion services and post-abortion care. This can include (but is not limited to) any of the following:</p> <ul style="list-style-type: none"> <li>• Number of safe and legal abortion services obtained by vulnerable women and girls in low- and middle-income countries</li> <li>• Number of sites that provide safe abortion products and/or services</li> <li>• Number of health professionals trained to provide safe abortion</li> <li>• Number of health professionals providing safe abortion services</li> </ul>
Development of new method of safe abortion	<p>Scientific evidence of a new drug, formulation, or prototype for safe abortion that provides one or more significant improvements over existing methods in:</p> <ul style="list-style-type: none"> <li>• Stage of gestation at which it can be effectively administered</li> <li>• Effectiveness at terminating pregnancy</li> <li>• Ability of women and/or girls to access and self-administer with greater autonomy and privacy</li> <li>• Ease of compliance (e.g. single pill administration)</li> <li>• Reduced side effects and pain</li> <li>• Stability profile and availability at decentralized locations</li> <li>• Permissive in context of restrictive regulatory frameworks (e.g., it has other primary indications)</li> <li>• Cost effectiveness</li> </ul>