# Accelerating Innovation in Vaginal Formulations in Support of Women's Health

## **Grand Challenges South Africa Request for Proposals**

# Applications due no later than December 16, 2025, 11:30 a.m. U.S. Pacific Time (8:30 p.m. South Africa Standard Time)

This RFP is jointly launched by several Grand Challenges funding partners, including Grand Challenges Africa (Science for Africa Foundation), Grand Challenges Brazil (Brazilian Ministry of Health and the National Council on Research), Grand Challenges India (Biotechnology Industry Research Assistance Council), and Grand Challenges South Africa (South African Medical Research Council). Each RFP may differ in its geographic focus, topic areas, and funding levels. Please review the eligibility criteria and specific requirements for each RFP carefully. The individual RFPs are listed separately [here]. If you qualify for more than one, we encourage you to apply to the RFP that best aligns with your proposed project.

Before applying, applicants should familiarize themselves with the supporting documents for this Grand Challenge, including the Rules and Guidelines, Application Instructions, and Frequently Asked Questions.

If you are planning to apply to this RFP, we will be hosting a dedicated webinar on November 20, from 6:00 to 7:00 AM Pacific Time. This session will provide a comprehensive overview of the RFP details and an opportunity to have your questions answered. To participate in the webinar, please register and submit your questions in advance. If you cannot attend live, the webinar will be recorded and available on this challenge page after the session.

# Background

# (Summary overview answering the question "why now?")

Local delivery of drugs into the vagina for prevention and treatment of female-specific conditions remains understudied and under-utilized despite clear potential advantages such as discreetness, potent local efficacy, large surface area for drug absorption, high potential for API dosage sparing, potential for fewer systemic side effects, as well as providing autonomy and empowerment of women. Several key drivers may be responsible for this lag, including paucity of mechanistic biological data, particularly from high-burden settings such as low- and middle-income countries (LMICs), to support the development of specific formulations for vaginal use as well as a persistent misconception that vaginally delivered products may not be embraced by women and their sexual partners. Several of our priorities for impactful products for sexual and reproductive health will require vaginal delivery for immediate, on-demand use. We seek to catalyze the development of innovative technologies and approaches that can safely and effectively deliver a wide range of vaginal products. We expect these approaches to have user appeal, including promotion of self-care capability and other beneficial features that women seek, hence the need to couple discovery research with high-quality end-user input.

### The Challenge

We are soliciting applications that contribute to development of vaginal formulations that promote optimal drug delivery within the vaginal compartment while positively supporting the vaginal milieu, and that also possess beneficial effects, even if unrelated to the API intended effect, that a user might consider desirable, such as enhancement of sexual pleasure. We anticipate identifying

product-agnostic features that promote vaginal health and that broadly appeal to women to advance product development and formulations for women's health. We welcome innovations at any stage of development that meet the scope of this call.

Applicants may apply to address one or more of the following objectives of this challenge:

- 1. Leverage biology for vaginally administered products: In this objective, we seek: 1) innovative formulations and delivery approaches that leverage the biology of the vaginal microenvironment to support development of novel delivery technologies and that have high potential for scalable, low-cost manufacturing options; and 2) novel components that could be incorporated into and improve existing formulations (e.g. films, tablets/inserts) that would promote maintenance of or transition to an optimal vaginal microbiome and/or promote other benefits to the vaginal mucosal epithelium. Specifically, we seek to assess and de-risk novel approaches to vaginal delivery that can leverage and support features of the vaginal milieu including mucus, host cells and microbes for drug delivery and as such we anticipate proposals including evaluation of the impact of these novel approaches or components on changes in the microbiome and vaginal host components (cells/cytokines, mucins, glycans, lectins, etc.).
- 2. Define characteristics of an ideal vaginal product: In this objective, we seek to support qualitative studies aimed at identifying and understanding specific features of a vaginally administered product that would most appeal to women such that many women, especially those of reproductive age in LMICs, would seek to use such a product (for example, 'what would you hope to achieve when using this product in your vagina?'). We are particularly interested in defining ancillary benefits (such as odor control, sexual enhancement, etc.) that could be derived from a vaginally delivered product that would likely not be supported by other routes of administration, as well as identifying major hurdles that may prevent a woman from seeking out or preferring a vaginal product. We acknowledge that there may be regional, cultural, demographic, or other preference differences, and are seeking to identify desires or barriers that are commonly expressed by women across these demographic differences. Applicants may propose methods to prioritize preferences such that the vaginal product developed can benefit as many women as possible. In sum, we aim to gather insights into preferred and achievable characteristics that would transform vaginal products from 'tolerable' to 'desirable.'

#### **Funding Level**

Projects with a duration of up to two years and a maximum requested budget of Up to \$250,000 USD (~R4.5 million) per project are eligible for funding. **Exploratory projects with shorter durations/lower budgets that focus on high-risk, innovative areas are strongly encouraged and will be given priority**. Budgets should be commensurate with the scope of work proposed and in line with allowable costs of the targeted funding organization for which the applicant is eligible. Indirect costs should be included in the budget and should not exceed **5**% of the total award (subject to the **SAMRC Terms and Conditions of funding**).

# **Eligibility Criteria**

This initiative is open to research institutes, NGOs, academic institutions, government agencies, and for-profit companies, with priority given to women-led projects and collaborations based in

low- and middle-income countries (LMICs). Projects must be based in South Africa and led by South African principal investigators, who are citizens or permanent residents. All applicants are expected to comply with the Foundation's global access clause. Applicants are encouraged to build upon existing or complementary projects, studies, or trials, and to engage in collaborations with other institutions. Applications from teams led by women and/or researchers at LMIC-based institutions or involving collaboration with women-led or LMIC-based organizations, are strongly encouraged. Only individuals applying through a legally recognized corporate entity are eligible.

## We are looking for proposals that:

- Focus on vaginally delivery approaches that do not require retrieval and disposal after use and can be adapted for extended- or slow-release of active ingredients.
- Use innovative, rigorous qualitative approaches that improve or deepen our understanding of standard acceptability metrics.
- Generate biological or end-user data from low- and middle-income regions and comply with national regulations on data security, data protection, and privacy.
- Propose rigorous scientific approaches to study a clear research question and whose rationale is clearly supported by peer-reviewed literature.
- Demonstrate feasibility with preliminary data in support of the proposed approach; if no preliminary data exists then the proposal should be limited in scope.
- Request the appropriate funds and time to achieve the objectives of the proposed work.
   Exploratory projects of lower cost but higher risk are strongly encouraged and will be prioritized.
- Promote a diverse, inclusive, and supportive research environment, with priority for collaborations involving LMIC-based experts in reproductive health.

# We will not fund proposals that:

- Evaluate the impact of currently available vaginally inserted products on the vaginal milieu (e.g., menstrual products, contraceptive devices, over-the-counter probiotics, etc.).
- Focus on approaches that would not be feasible or affordable in low- and middle-income countries, including personalized medicine. If these approaches are included, the feasibility of scalable, low-cost development should be explicitly stated.
- Focus on the development of therapeutics or interventions for specific conditions, such as treatment for STIs or contraceptive products. While these types of interventions may be used as a test case within the proposal, the work itself should focus on formulations.
- Are focused solely on basic exploratory scientific research without a clear translational pathway, including potential end-use scenarios, scalability considerations and regulatory or manufacturing implications.
- Center solely on focus groups and interviews. These methods or qualitative approaches
  are acceptable if embedded within rigorous mixed-methods study designs that generate
  quantitative, actionable insights beyond anecdotal data or standard acceptability metrics
  such as affective attitudes.
- Do not consider end user preferences or assume end-user preferences. For the purposes of this RFP, end-users can be defined as women of reproductive age in low- and middle-income countries. Proposals may focus on subgroups (e.g., adolescents, post-partum women), but the target group must be explicitly defined and justified.
- Primarily depend on traditional acceptability questionnaires or surveys (e.g., "if x hypothetical product existed, how interested would you be in using it?").

- Do not directly address one of the core objectives as outlined above.
- Can not be accomplished within a two-year maximum project duration or within the stipulated budget maximum.
- Support researchers or research teams who are affiliated with the tobacco industry, or who receive (or are applying for) funding from the tobacco industry, which includes manufacturers and distributors of e-cigarettes or vaping products.

# **Application Submission**

All applications must be submitted **directly through the Grand Challenges South Africa online portal (RedCap)**: <u>GCSA Women's Health Innovation Call</u>. (Submissions via email or any other method will **not** be accepted).

Applicants are required to complete the following within the portal:

- 1. Project Proposal Complete all registration fields, including the Applicant Profile.
- 2. **Uploads** Applicants must provide the following documents:
  - Full Proposal Proposal Template (Signed by the institution)
  - Budget Upload as a Microsoft Excel or PDF file using the <u>official budget template</u>. provided in the RFP.
  - Curriculum Vitae (CVs) Upload CVs for the Principal Investigator and all Coinvestigators.

# **Submission Requirements:**

- Proposals must comply with all formatting and file size limits specified in the RFA.
- Applications must be complete, responsive, and submitted by the deadline.
- Applicants must meet all SAMRC eligibility criteria (e.g., South African PIs, citizens, or permanent residents).

For questions regarding the RFP, selection criteria, or application instructions, applicants can contact **Karabo Kgomo | SAMRC Karabo.Kgomo@mrc.ac.za )** for South Africa–specific guidance.

#### **Budget Guidelines**

- Budgets submitted must include all applicable taxes.
- South African applicants must prepare budgets in South African Rands (ZAR).
- Applicants from other eligible countries may prepare their budgets in South African Rand or USD, noting that the exchange rate for awards will be based on the USD/ZAR rate at which the SAMRC received the funds.
- All direct line items must be auditable.

# Allowable costs:

- Personnel: Soft-funded posts for individuals working on the project (e.g., post-docs, students, technicians, project managers) will be funded, provided an accurate estimation of time allocation is provided, and they are not already funded by other means.
- Consultants: Local and/or foreign consultants providing a service or capability not available among project partners but essential for the completion of project deliverables.
- Equipment: Partial or full support for the cost of equipment directly required for the project. Budget limitations may apply.
- Supplies, consumables, and other direct laboratory or research costs.
- Sub-contracts: Any local or international organization providing essential services or capabilities not available among project partners.

- Travel and accommodation directly related to the project's execution.
- Institutional overhead: An indirect cost rate of 5% is allowed.

#### Non-Allowable Costs:

- Salaries of permanent or fixed-term staff, e.g., tenured staff, professors, etc. That is fully covered by the host institutions.
- Purchase or construction of buildings.
- Rental costs for space owned by the institutions participating in the project.
- Recruitment or retrenchment costs for staff.
- Purchase of office furniture.

# **Review and Evaluation of Proposals**

# **Eligibility Screening:**

- All applications will be screened by the SAMRC and Grand Challenges funding partners for completeness and responsiveness to the call and its administrative requirements/provisions.
- Incomplete or non-responsive applications, or those submitted after the deadline, will not be processed further.

#### **Evaluation:**

All eligible applications will be reviewed by local and international experts, considering at least the following criteria:

- Significance / Relevance / Impact: Potential impact on public health outcomes.
- Approach: Innovation, rationale, work plan, and cost-effectiveness.
- **Team:** Size, reach, experience, and complementarity of project partners.
- **Environment:** Availability of infrastructure, equipment, and resources; unique features of the project environment, subject populations, or collaborative arrangements.

## Timeline

Milestone	Date
RFP Launch	Tuesday, 28 October 2025
Application Close	Tuesday, 16 December 2025, 8:30 p.m. SAST
Review & Approvals	Jan – March 2026
Notification of Awards	April 2026
Anticipated Project Start	April/May 2026

#### **Additional Information**

- Ethics and regulatory approvals must be obtained before disbursement.
- Funders may verify information provided by applicants.
- No responsibility for costs incurred in preparing applications.
- Funders may amend or withdraw the RFP at any time.
- Successful applicants may be asked to address reviewer comments or negotiate budgets.

# **Contact for queries:**

Karabo Kgomo | SAMRC Karabo.Kgomo@mrc.ac.za