GHIT Fund Proposal SAMPLE
Reference Number: GHIT-RFP-2013-XXX

This sample proposal is provided for your reference. All of the content and names are fictional. Please note that this sample proposal includes items such as executive summary and contact information that we will ask you to type directly into the online submission system. You will also be asked to upload 1. Proposal template (Word format), 2. Timeline template (Excel format) and 3. Budget template (Excel format) and, if necessary, other relevant documents to the system as attachments.

Explanatory 'call-outs' have been included to point out the content that specifically addresses the information requested for each section.

Instructions

Proposals are required to address all sections outlined below using no more than 25 pages, including all attachments with the exception of CVs. CVs should not exceed 2 pages per person. Proposals exceeding 25 pages will be returned to the applicant.

Title

Development of a Linafovir–Sachaviroc combination microbicide vaginal ring for the prevention of HIV/AIDS

Executive Summary

Describe the proposed partnership between Japanese and non-Japanese organizations. Include a brief discussion of the motivation for collaboration.

The Linafovir-Sachaviroc vaginal microbicide ring is an approved preclinical candidate in the portfolio of the Women's Health Initiative for HIV/AIDS (WHIH). WHIH and Yoshi Pharmaceuticals propose to collaborate to progress this candidate to Phase 1 clinical studies in Tanzania to assess the safety and pharmacokinetics of both drugs when used in combination in a vaginal ring. This project will leverage the broad and deep experience of WHIH in conducting clinical trials in developing countries as well as Yoshi Pharmaceutical's years of experience in developing and licensing HIV treatment and prevention drugs, including Linafovir and Sachaviroc. Both organizations have been dedicated to developing interventions important for treating and preventing HIV. The motivation for this project is to leverage the strengths of both WHIH and Yoshi Pharmaceuticals to address an unmet need of protection for women.

The first paragraph provides a brief overview of the project and the partnership.

The next two paragraphs describe the strengths of each partner, and their shared motivation for developing interventions to treat and prevent HIV.

Partnership Management

Complete the following table detailing partner information. If there are more than three partners, provide information in a similar format.

	Designated Grantee*	Collaboration Partner 1	Collaboration Partner 2
Organization Name	Women's Health Initiative for HIV/AIDS	Yoshi Pharmaceuticals	
Organization Type (e.g., PDP, pharma company, academic institution) Designated Grantee (Please choose one organization)	PDP	Pharmaceutical Company	
Organization Status	☐ Japanese ☒ Non-Japanese	☒ Japanese ☐ Non-Japanese	☐ Japanese ☐ Non-Japanese
Mailing Address	1302 Thomas Circle, Suite 300 Washington, DC 20005 U.S.A.	2-4, Hongo, Bunku, Osaka 436-1428 Japan	
Contact Person's Name and Title	Julie Austen	Takumi Watanabe	
Email Address	Juliea@whih.com	twatanabe@yoshipharma.com	
Telephone Number	Tel: +1-202-887-9864 Mobile: +202-707-7127	Tel: +81-2-5432-1256 Mobile: +81-70-3289-3212	

* The designated grantee will be the funding recipient and will be responsible for the performance of its collaborating partners. A representative of the designated grantee will serve as the main point of contact with the GHIT Fund and will be responsible for all GHIT Fund discussions and negotiations.

Partner Roles & Responsibilities

Detail the roles of the designated grantee and the collaborating partner(s) and the decision making processes for the project.

WHIH will be the designated grantee for this project and is responsible for leading, coordinating and monitoring the clinical study in Tanzania. Tanzania was chosen as the clinical trial site because WHIH has a team in this location and this will ensure an effective and closely monitored trial. In addition, WHIH is responsible for delivering the work plan in accordance with the agreed timeline and budget, and is responsible for completing all GHIT reporting. The project team will be led by WHIH (Principal Investigator) with project team members from both organizations.

The first two paragraphs describe the designated grantee and the role of each partner in this project.

Yoshi Pharmaceuticals will be responsible for producing clinical trial materials and providing advice on clinical development. Yoshi Pharmaceuticals and WHIH have already jointly designed the clinical trial study design and methodology.

All project decisions are made through a Joint Executive Committee (JEC) made up of senior managers from both organizations. The JEC has a clear charter regarding decision-making and a process for resolution if consensus can't be reached. The decision to move forward to Phase II studies will be made by the JEC after thorough review of the Phase I data.

The last paragraph describes the process for how project decisions will be made.

Partner Qualifications

Summarize the qualifications of each partner organization and how they relate to the project.

WHIH is a product development partner that has become an important player in the microbicide field over the last 10 years. They have an established track record in evaluating HIV compounds, conducting and monitoring clinical trials (Phase I, II and III studies), and identifying appropriate regulatory pathways for product licensure.

WHIH has supported its partners in developing and licensing two antiretroviral therapy treatments for HIV in the last seven years. WHIH currently has over nine products in its pipeline. WHIH has a scientific team of project directors who have core technical capabilities in the HIV plus access to a wide range of technical experts as consultants.

Yoshi Pharmaceuticals is a global pharmaceutical company with a successful track record in the discovery and development of novel drugs. Yoshi Pharmaceuticals' portfolio of products and pipeline of investigational drugs includes treatments for HIV, hepatitis, respiratory, cardiovascular, cancer and inflammatory diseases.

A partnership with Yoshi Pharmaceuticals and WHIH comprise all the needed skills and capabilities necessary for the successful delivery of this project.

The organizational credentials and relevant experience have been provided for both partner organizations.

Partner History

If the partners have previously worked together, provide a brief description of your collaboration history.

Yoshi Pharmaceuticals and WHIH have partnered to conduct clinical trials on two previous occasions. Successful partnership on two Phase I safety studies have been conducted for Linafovir and Sachaviroc delivered as a monotherapy drug in a vaginal ring to HIV-uninfected, sexually abstinent women in Malawi and Tanzania, respectively.

The response lists the previous projects conducted by these collaborating partners.

Contractual Relationship

Prior to receiving funds for a grant award, the GHIT Fund requires a contractual relationship between collaborating partners. Describe your partnerships' existing or intended contractual relationship.

Yoshi Pharmaceuticals and WHIH have had a collaborative contractual agreement in place since 2009. A copy of the contract may be provided upon request.

If this current grant is funded, an amendment to the current collaboration agreement will be created to specifically include detailed contractual agreements for conducting the Phase 1 study. Both organizations have previous experience negotiating such amendments to their current contract.

The response provides details of an existing contract. Information has also been included to make clear that additional contractual arrangements for the current study will be seamless.

Principal Investigator

Provide information on the project's Principal Investigator (PI). The PI may be different than the main point of contact.

Name	Jane Smith
Title	Associate Director
Organization	Women's Health Initiative for HIV/AIDS (WHIH)
Telephone Number	201-345-6563
Email Address	Janes@whih.com

Collaboration Contact

Provide information on the main contact person for the partnership collaboration:

Name	Julie Austen
Title	Chief Scientific Officer
Organization	Women's Health Initiative for HIV/AIDS (WHIH)
Telephone Number	201-345-8912
Email Address	Juliea@whih.com

Product Development Proposal

Scope

(Please check all that apply)

Disease	Intervention	Development Stage
☒ HIV/AIDS ☐ Tuberculosis ☐ Malaria ☐ Other Neglected Tropic Diseases (NTDs)	☒ Drugs ☐ Vaccines ☐ Diagnostics Intervention Name: Linafovir-Sachaviroc microbicide vaginal ring	☐ Pre-clinical ☒ Clinical ☐ Licensure

Scientific Rationale

Describe the scientific rationale for pursuing this intervention.

Linafovir, a nucleotide analog HIV-1 reverse transcriptase inhibitor and an HBV reverse transcriptase works by stopping the virus from copying its genetic material once it enters a healthy cell. Sachaviroc is a CCR5 receptor antagonist which works by blocking the CCR5 receptors on healthy immune cells, preventing HIV from entering and infecting the cells.

Combination microbicides that target different points in the HIV life cycle have been shown to be less likely to develop resistance.[1] The rationale for a combination microbicide is based on results from highly active antiretroviral therapy (HAART), which have demonstrated the benefit of antiretroviral combinations in the treatment and prevention of HIV infection.[2]

Several randomized, placebo-controlled clinical trials have shown that Linafovir combined with at least one other potent new antiretroviral (including Sachaviroc) is highly effective in reducing viral load to below the limit of detection.[3] Therefore, Linafovir-Sachaviroc is a likely efficacious combination for HIV prevention delivered in a vaginal ring.

A summary of the scientific rationale for use of the combination therapy is provided, along with a brief description of supportive data on the combination of these two drugs. Key references have also been included.

1 Ju Y, et al. Combination Microbicides. Microbicide Journal. 118-267. June 2012.

[2]Smith SD, Scott CJ. The renaissance of fixed dose combinations: Linafovir. The Clinical Risk Management Series. 2007;3(4):579-83.

[3] Franklin BQ, et al. Effectiveness and safety of novel ARV combinations in treating HIV. Lancet (2010) 376: 2101

Objectives

List the project objectives.

Objectives of this project are to: 1) conduct a Phase I clinical trial to assess the safety and pharmacokinetics of Linafovir and Sachaviroc when used in combination in a vaginal ring, 2) to evaluate the acceptability and adherence of the vaginal ring in HIV-uninfected sexually abstinent women over 28 days of use, and 3) provide information on the dose range needed for Phase II.

The objectives are clear, measurable and linked to the project milestones.

Project Approach

Describe the processes or methods that will be leveraged to achieve the project objectives, including the supporting rationale.

The Phase I study will be conducted under current good clinical practices to ensure high quality of clinical trial execution.

The Phase 1 design is a double-blind placebo-controlled dose-escalation trial with a low-dose group and high-dose group (1:1 randomization). The low-dose group will contain 25mg Linafovir plus 50mg Sachaviroc, and the high-dose group will contain 50mg of Linafovir plus 100mg of Sachaviroc. These doses were based on oral combination doses and previous Phase I studies of each product as monotherapy in vaginal rings which provided key pharmacokinetic information. Each dose group will be tested in 22 healthy, HIV-uninfected, sexually abstinent women between the ages of 18-40 years old for a period of 28 days. The clinical trial site is in the Mbeya Municipality, Tanzania which has previous experience in conducting HIV trials.

The results of the Phase I combination study will provide the critical information needed to rapidly advance the Linafovir-Sachaviroc vaginal combination ring into Phase II to support the overall goal of providing women with an important HIV prevention tool.

Information is provided on the way the clinical trial will be conducted, the trial design, the trial site, and the importance of the trial results for supporting the long-term objective.

Development History

Accomplishments to Date

If an existing project, summarize its history, major milestones, and achievements to date. Include peer reviewed publications and patents, if any.

Yoshi Pharmaceuticals and WHIH completed the preclinical studies on Linafovir-Sachaviroc in March 2013. A comprehensive preclinical package was included in an IND and Investigator's Brochure to support the Phase I study. The preclinical package included 30 day toxicology studies in two species (mouse, and dog) and extensive pharmacokinetic studies to determine the pharmacokinetic profile of the drug combination.

A summary of the key information supporting the Phase I study has been provided along with a brief description of relevant patent and publication status.

Both drugs have composition-of-matter patents issued to Yoshi Pharmaceuticals. A patent has been filed and is pending for the use of these drugs in combination.

To date, no peer-reviewed papers have been published on the use of these drugs in vaginal rings.

Funding History

List all previous and current confirmed sources of funding for this particular project, both financial and in-kind support. If there are more than two sources, provide information by adding additional columns to the table below.

	Source 1	Source 2
Resource Type (e.g., $¥, FTEs)	$ and in-kind contribution	
Funding Source	WHIH	
Funding Amount	USD $250,000	
Support Timeframe	2013-2014	
Funding Focus	Phase 1	

List other funding sources being sought for this project, if any.

None at present

Independent Scientific/Technical Reviews to Date

The GHIT Fund will consider Independent Review Committee findings when evaluating proposals. If this project has been previously reviewed, provide the organization or group that completed the review and attach a copy of the full review, including conclusions and recommendations.

Reviewing Organization	Review Date
WHIH Expert Scientific Advisory Board	This project was approved in May 2012.
WHIH Expert Scientific Advisory Board	The clinical protocol was approved in August 2013.

Development Plan

Activity Timeline

Attach a Gantt chart, using the *GHIT Fund_RFP_GanttTemplate.xls* template. The timeline should summarize the following elements.

- Planned project milestones: the events that measure progress against the project objectives defined above
- Activities: the steps that are needed to achieve the project milestones
- Activity duration and timing

Milestones

Identify key milestones for tracking project progress and the target date for achieving each milestone. Assuming a milestone has been reached, describe what criteria will be used to determine if the project advances to the next activity. Grantees will be expected to submit annual reports describing progress against these milestones. Indicate the year in which the milestone progress will be reported.

Milestone	Target Milestone Date	Criteria for Advancement	Expected Reporting Year
Enroll 44 subjects in Phase I double-blind, placebo-controlled dose escalation trial	11/1/2014	44 subjects enrolled within 6 months of site initiation.	☒ Yr 1 ☐ Yr 2
Demonstration of safety and adherence after 1 month of treatment and follow-up.	3/31/2015	An acceptable safety profile compared to placebo. No SAEs or unexpected AEs that would raise concerns. Adherence of ≥ 90% during the treatment period	☐ Yr 1 ☒ Yr 2
Demonstration of acceptable plasma concentrations.	3/31/2015	Plasma concentrations of <100ng/ml will be considered acceptable.	☐ Yr 1 ☒ Yr 2

The milestones and criteria for advancement are clear & measurable.

For grants that include a clinical trial, a clinical trial report is not an acceptable milestone. Specific data used to determine advancement must be defined.

Risk Mitigation Plan

Identify scientific and technical, governance, operational, and financial risks which may affect the successful completion of the project and the proposed risk mitigation plan.

Potential Risk	Mitigation Plan
Scientific and Technical Risks (e.g., non-standardized assays, protocol deviations)	
Protocol deviations from the study protocol	WHIH would add appropriate amendments to the protocol.
Identified site may have delays in patient enrollment	WHIH would add an additional site if needed. Adding an additional site would increase the cost of conducting the clinical trial. If this occurs, the partnership would actively seek other funding sources to complete the trial.
Governance Risks (e.g., partnership viability, IP disputes)	
Changes in senior leadership resulting in less support	If leadership changes, each partner would invest in building strong relationships to keep commitment high.
Operational Risks (e.g., clinical supply availability; protocol deviations; time delays)	
Competition to enroll subjects due to other competitive trials	WHIH would add an additional site if needed. The clinical site principle investigator is very experienced and will work closely with WHIH to monitor clinical trial enrollment.
Financial Risks (e.g., insufficient funding, cost overruns)	
Insufficient funding to conduct clinical trial.	The partnership would actively seek other funding sources to complete the trial.

The responses identify the major risks in the four listed categories, and appropriate means to prevent or manage the risks, should they occur.

Protections

The GHIT Fund and its grantees must abide by accepted international ethical guidelines. Provide partnership plans for assuring responsible conduct of research, good clinical practice, information privacy and security, and, if applicable, protection of animal and human subjects. If the project is exempt or has already been approved by an appropriate ethics review committee (such as an Institutional Review Board), submit supporting documentation.

All WHIH projects are reviewed annually by an independent Expert Scientific Advisory Committee. The protocol will be reviewed and approved by the Tanzania IRB. The study will be conducted at a reputable and experienced site according to International Conference on Harmonisation (ICH) of good clinical practice guidelines.

WHIH's R&D strategy, target product profiles, the development pathway and decision criteria are transparent and publicly available on WHIH's website. At each stage of development, relevant safety, efficacy and pharmacokinetic data are reviewed. Feasibility of production and cost of goods are also key considerations throughout the development process.

The response addresses how the project will be reviewed by appropriate ethics review boards and the measures that will be taken to adhere to international standards for conducting clinical trials.

Project Team

Project Staff Roles & Responsibilities

List *key* project staff and their roles.

Name	Organization	Project Role
Jane Smith	WHIH	Project Leader/Principal Investigator
Annabelle Sanchez	WHIH	Clinical Pharmacologist
Maria Hogan	WHIH	Chief Medical Officer
Barbara Yang	Consultant	Microbicides Expert
Alex Westfall	WHIH	Principal Investigator – conduct combination therapy microbicide trials
Nuru Alley	WHIH	Principal Investigator – conduct combination therapy microbicide trials (from Tanzania)
Takumi Watanabe	Yoshi Pharmaceuticals	Support with advice on clinical development
Yamato Kobayashi	Yoshi Pharmaceuticals	Manage project team who is making clinical materials
Yukki Saitou	Yoshi Pharmaceuticals	Support with advice on clinical development

Staff Qualifications

Summarize *key* team member qualifications relative to the project objectives.

Name	Qualifications
Jane Smith	Jane Smith serves as WHIH's director of formulation technology, directing formulation and manufacturing sciences of vaginal rings, gels and films. Dr. Smith received her BS in biology, chemistry and mathematics from John Hopkins University and her medical degree from the University of Philadelphia. In 2006, Dr. Smith was named principal investigator for MTN, an HIV/AIDS clinical trials network established by the National Institute of Allergy and Infectious Diseases. Prior to joining WHIH, Dr. Smith worked at the global pharmaceutical company Sanofi-Aventis for seven years, during which she served as the assistant director and group leader as well as the senior manager and head of the Pharmaceutical Sciences Department. In those roles, Dr. Smith was responsible for directing formulation development of solid and semi-solid dosage forms for global markets, and for packaging development of therapeutic compounds.
Annabelle Sanchez	Annabelle is a clinical pharmacologist working on the clinical development of microbicides from candidate selection to Phase III clinical studies. Annabelle previously worked with Gilead Sciences and Novartis in the United States. She is a registered pharmacist and holds a PHD in pharmaceutical sciences from Cornell

The team member qualifications include such key relevant data as educational background, history of successful work on similar projects, and the unique skills that staff bring to the project.

	University.
Maria Hogan	Dr. Hogan is a professor of obstetrics and gynecology at the College of Health Science at the University of Zimbabwe in Harare. Her main research interest is HIV prevention clinical trials in women with particular emphasis on microbicides and pre-exposure prophylaxis development in low resource settings. She is also principal investigator for a large US National Institutes of Health-funded HIV clinical trials unit that is executing clinical trials for two networks. She is the protocol co-chair for a large HIV prevention trial (MNH 007, EMPOWER). Dr. Hogan has also evaluated HPV screening and he is currently following a cohort to establish HPV types among Zimbabwean women with invasive cervical cancer.
Barbara Yang	Dr. Yang is professor and vice chair for Faculty Affairs and director of infectious disease research in the Department of Obstetrics, Gynecology and Reproductive Sciences, University of Pittsburgh School of Medicine. Dr. Yang received her undergraduate and doctoral degrees in bacteriology and public health from Washington State University. Dr. Yang is author or co-author of more than 150 articles and abstracts in the medical literature and a former president of the Infectious Diseases Society for Obstetrics and Gynecology. She is on the board of the International Society for HIV Disease Research. Dr. Yang is on the editorial boards of medical journals, including Infectious Diseases in Obstetrics and Gynecology and Sexually Transmitted Diseases.
Alex Westfall	Dr. Westfall is the Head of Laboratory at the London School of Hygiene and Tropical Medicine. Dr. Westfall holds an MD from the University of Berkeley (1995) and a B.S. in Biology from the University of Michigan. He directs a research group working on the pathogenesis and transmission of HIV infection, with a particular emphasis on the development of prevention strategies applicable to the developing world. His research group has been instrumental in elucidating the early mechanism of HIV transmission, which is being used in a translational fashion to develop safe and effective vaginal microbicides and to explore novel HIV vaccination strategies.
Nuru Alley	Dr. Alley is responsible for WHIH'S clinical trials and international clinical site development. Dr. Alley obtained a bachelor's degree (B.Sc.) in clinical pharmacology from the University of Stellenbosch, South Africa. She earned her PhD and qualified as a medical doctor at the University of Nairobi Medical School. Previously, Dr. Alley worked as an independent clinical research consultant in the drug development process. She has significant experience in all levels of clinical research and in a broad range of therapeutic areas, and she has worked as an investigator in clinical research for more than 22 years. Prior to joining WHIH, she worked as a medical officer in numerous therapeutic areas and lectured in pharmacology and

	toxicology at the University of Nairobi Medical School.
Takumi Watanabe	Takumi Watanabe is the Head of Pharmaceutical Technology Research & Development Laboratories at Yoshi Pharmaceuticals since 1992. He holds a BS and an MS from the Faculty of Pharmaceutical Science in University of Tokyo, and a PhD from the Faculty of Pharmaceutical Science at Osaka University.
Yamato Kobayashi	Yamato Kobayashi is the General Manager at Yoshi Pharmaceuticals. He holds a BS and an MS from the Faculty of Pharmaceutical Science in Kyoto University, and a PhD from the Faculty of Pharmacy at Keio University.
Yukki Saitou	Takumi Watanabe is the Division Head of Infectious Diseases at Yoshi Pharmaceuticals since 1992. He holds a BS and an M.S from the Faculty of Pharmaceutical Science in Hiroshima University, and a PHD from the Faculty of Pharmacy at Kyushu University.

Attach CVs of no more than two pages for each *key* team member.

Project Budget

Please provide a narrative to describe your attached budget, including justifications for the overall amount and the costs for each milestone.

WHIH and Yoshi Pharmaceuticals are requesting 102,136,364 JPY from GHIT to accomplish the defined milestones for this project.

To meet milestone 1 of conducting the double-blinded placebo controlled dose escalation trial in Tanzania in year 1, we require two Principal Investigators and a Microbicides Expert (26,112,150 JPY). Since the clinical study will be performed in Tanzania, one of the PIs from the United States and the microbicide expert will need to travel to have face-to-face meetings to audit the clinical trial site, monitor progress, and review results. These necessary travel expenses are also requested (2,180,000 JPY). To perform the clinical trial, we will need materials and supplies such as the microbicide vaginal rings, culture wares, plastic disposables, cells, and various assay kits (457,050 JPY). In addition to those expenses, other costs such as Regulatory Fee to Tanzanian Authorities, Clinical Trial Insurance and medical indemnity insurance for the PI need to be included (1,050,000 JPY).

To complete the 2nd and 3rd milestones of demonstrating adequate safety, adherence, and pharmacokinetic data from the completed trial in year 2, the two PIs and Microbicide Expert will still be required (2,731,143 JPY). In addition, we will need a data manager to analyze the data from the clinical trials (1,481,630 JPY). Study report materials will also be required to complete this milestone (494, 060 JPY).

The total cost of this project is projected to be 126,830,264 JPY. Because WHIH has committed 24,693,900 JPY to this project, Yoshi Pharmaceuticals and WHIH are requesting 102,123,764 JPY.

The budget narrative provides a clear description of the need for the requested resources. The response is specific to the milestones as they are written in the proposal, timeline and budget. Justifications for milestone line items have been included.

Applicants are also required to submit a project budget using the *GHIT Fund _RFP_BudgetTemplate.xls* template. Provide the budget as an attachment to this proposal.

Global Health Impact and Access

Global Health Need and Impact

Describe how the project will address a specific global health need and how it will impact that need in the short and long term. What are the unique contributions this project will make? Include references as footnotes.

HIV/AIDS is one of the greatest threats to people all over the world, especially women. Every day, more than 3,000 women are newly infected with HIV globally. Women and girls are particularly vulnerable to infection due to a mix of biology and social realities, yet they lack the tools they urgently need to protect themselves. In Sub-Saharan Africa, women 15-24 are at least twice more likely to be infected with HIV than young men.[4] Safe and effective microbicides have the potential to address one of the central gaps in current HIV prevention strategies.[5] A vaginal combination ring can help women protect themselves from infection and take their health into their own hands.

The results of previous clinical trial studies emphasize the need to identify alternative delivery systems that may improve adherence to antiretroviral-based preventative therapies. The results showed that prevention of HIV acquisition was related to adherence; low adherence to vaginal gels was common. Reduction of HIV acquisition in the group with greater than 80% adherence was 54%, whereas the reduction in the group with less than 50% adherence was 28%.[6]

The Linafovir-Sachaviroc vaginal ring has the capacity to release drugs over longer periods of time and therefore may decrease user lapses in adherence. Additionally, by releasing more than one drug at a time, the ring is expected to reduce the risk of drug resistance. Based on these studies and the efficacy of both Linafovir and Sachaviroc, Linafovir-Sachaviroc vaginal combination ring has the potential to be an effective HIV prevention tool for at risk populations and address an important unmet need.

This project represents the second combination therapy in a vaginal ring currently in clinical trials. Although this combination ring targets the same pathways as the other existing combination therapy Dapivirine-Maraviroc, the Linafovir-Sachaviroc combination therapy is more potent and therefore costs less. In addition, this combination therapy is expected to be priced lower than the Dapivirine-Maraviroc ring for countries in the developing world.[7]

A brief description of the global health problem, with key references, is included as background.

The response establishes a clear need for a delivery method (vaginal ring) that has the potential to increase adherence and therefore, improve efficacy.

The final paragraph details the potential for a lower cost combination therapy vaginal ring as an intervention choice for HIV prevention.

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[4] *http://www.ipmglobal.org/publications/first-combination-arv-vaginal-ring-hiv-prevention-phase-i-safety-trial*
[5] *Mauck C, Weiner D, Lai J. Effectiveness of Microbicides. Microbicides Journal 2012.*
[6] *Abdool Karim Q, S Frohlich JA, et al. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. Science 2010; 329(5996):1168-74.*
[7] *Alan N. Microbicides in the prevention of HIV infection: current status and future directions. Drugs 2010;70(10):1231-43.*

Global Disease Priority

Describe how the project supports the current global disease priority or strategy. Include references as footnotes.

This project supports two of the overarching strategic goals provided by the World Health Organization (WHO) on HIV/AIDS: 1) to optimize HIV prevention, diagnosis, treatment and care outcomes and 2) to address inequalities and advance human rights. Despite the current progress, existing HIV prevention options have not done enough to stop the spread of HIV among women. Present methods may be unrealistic for women who are unable to negotiate with their male partners to use condoms and remain faithful.

The Linafovir-Sachaviroc microbicide combination ring could empower women with a long-acting, discreet tool to protect themselves from infection. Because the ring only needs to be replaced once a month, it has the potential to provide long-acting protection.[8] The vaginal ring is also convenient and discreet, physically stable, durable and easy to distribute, making them suitable for use in developing countries. Studies also show that the ring is acceptable to women in Africa, where the need is most urgent.

The response describes how the project fits within the HIV strategic goals of the global health community as described by a leading international health organization (WHO).

The response also describes how the current project could potentially contribute to the global goals.

Global Access

Describe how the project is adherent to the principles and commitments outlined in GHIT Fund's Data and Product Access Policies?

This project will adhere to GHIT Fund's Data Access Policy by making the results of the Phase 1 trial publicly available through a published paper within a year of completing the trial.

This project will adhere to the GHIT Fund's Product Access Policy by providing access to this product through tiered pricing to ensure the lowest possible price to low income and low middle income countries.

GHIT Fund Data Access Policy
http://ghitfund.org/en/activities/support/data-access-policy/

GHIT Fund Product Access Policy
http://ghitfund.org/en/activities/support/product-access-policy/

The response references how this project plans to adhere to GHIT Fund's access policies.

[8] *Chu, Margaret. HIV Prevention Strategies in the Developing World. Health Policy. December 2012*

Proposal Checklist

☒ Project proposal using the *GHIT Fund_RFP_ProposalTemplate.doc* form

☒ Project Gantt chart using the *GHIT Fund_RFP_GanttTemplate.xls* form

☒ Project budget using the *GHIT Fund_RFP_BudgetTemplate.xls* form

☒ CVs of key project staff (no more than 2 pages per person)

☒ Independent Review Committee findings (if applicable)

☒ Ethics review board approval or exemption (if applicable)