Advancing Gender Equality through Evidence and Products that Empower Adolescent Girls and Women

Key results:

- Safe, affordable, effective microbicides and multi-purpose prevention technologies (MPTs) available to women where the need is greatest
- Secure regulatory approvals for monthly dapivirine vaginal ring (DVR) in areas where there is an identified need
- Support access and market implementation to drive the uptake of DVR as an additional HIV prevention option
- Implement a clinical bioavailability clinical trial along with supportive product development studies required for licensure
- Implement a clinical trial program along with supportive product development studies required for licensure

Justification for support:

- Women and girls urgently need HIV prevention methods that they can control to protect their sexual and reproductive health (SRH). This project recognises that meeting diverse user needs is essential to achieving a meaningful impact on HIV incidence and that women's SRH needs do not exist in isolation; therefore, providing both HIV prevention and MPT product options that women can choose from at different points in their lives is essential to supporting their overall health.

The project addresses the Danish development policy focus on reversing the global population trend. It also contributes to the commitments on:

- fighting for gender equality and girls' and women's rights;
- placing sexual and reproductive health and rights (SRHR) of women and girls at the centre;
- addressing underlying causes of vulnerability and contributing to building resilience to crises, natural disasters and climate change.

Major risks and challenges:

- Unstable political, funding and operating climate with reduced attention and funding available for adolescent and SRHR topics
- Project outputs are not used by decision makers and/or products are not integrated into global/national HIV prevention strategies
- Challenges securing regulatory approval, WHO and country government level support

Challenges establishing pathways and strategies for microbicide product access

THE ST	2022 254				
File No.	2023-251	54			
Country	Global	Global			
Responsible Unit	MNS				
Sector	Developr	nent; H	ealth		
Partner	Populatio	n Coun	ncil		
DKK million	2024	2025	2026	Total	
Commitment	10	10	10	30	
Projected disbursement	10	10	10	30	
Duration	2024-202	6			
Previous grants			400,000 DK	K from	
	1998-202	3.			
Finance Act code	06.36.03.3	11			
Head of unit	Karen Grønlund Rogne				
Desk officer	Marie My	Warbo	org Larsen		
Reviewed by CFO	YES: Ant	onio U	gaz-Simonsei	n	
Relevant SDGs Maxim	um 1 high	liaht mit	h aren7		

Relevant SDGs [Maximum 1 – highlight with grey]

1 mm ******** No Poverty	2 winds ((() No Hunger	Good Health, Wellbeing	4 touches Quality Education	5 fines Gender Equality	Clean Water, Sanitation
Affordable e Clean Energy	Decent Jobs, Econ. Growth	Industry, Innovation, Infrastructure	10 HEROTE SEQUENCES Reduced Inequalities	Sustainable Cities, Communities	Responsible Consumption & Production
13 Policita Climate Action	Life below Water	Life on Land	Peace & Justice, strong Inst.	17 Partnerships For Goals	

Objective

Generate cutting-edge, multidisciplinary research and tools; develop innovative sexual and reproductive health products; and systematically build bodies of evidence to enhance the health and well-being of adolescent girls and women

Environment and climate targeting - Principal objective (100%); Significant objective (50%)

	Climate adaptation	Climate mitigation	Biodiversity	Other
Indicate 0, 50% or 100%	0	0	0	0
Total green budget (DKK)	0	0	0	0

Justification for choice of partner:

The Population Council is an international research organisation with expertise in SRHR and related health and development issues, conducting research and programs for governments and civil society organisations in more than 50 countries. PC is a well-known partner to Denmark, having received numerous contributions in the period from 1998 – 2015 and again from 2020 - 2023. The acquisition of IPM in July 2022 gave PC the possibility to develop further its biomedical research, which this grant supports.

Summary:

The project enables the Population Council to continue to advance two important bodies of work:

- 1. The GIRL Center's evidence-generation and utilisation activities to inform policies and programmes to meet the multi-faceted needs of adolescent girls and young women (AGYW);
- 2. The Center for Biomedical Research (CBR)'s dapivirine vaginal ring (DVR) portfolio of HIV prevention products that meet the needs and preferences of women throughout their lives.

Budget:

Outcome 1: Advancing evidence-informed policies and programs to meet the multi-faceted needs of	15 DKK Million
adolescent girls and young women	
Outcome 2: Promoting women's sexual and reproductive health by developing, and ensuring access	15 DKK Million
Total	30 DKK million

Project Document for single-partner project:

Advancing Gender Equality through Evidence and Products that Empower Adolescent Girls and Women

Cover page (*)

See Appropriation Cover Note format.

1. Introduction

The present project document outlines the background, rationale, justification, objectives and management arrangements for development cooperation concerning 'Advancing Gender Equality through Evidence and Products that Empower Adolescent Girls and Women' 2024-2026 as agreed between the parties: The Population Council (PC) and the Department for Migration, Stabilisation and Fragility at the Danish Ministry of Foreign Affairs. The project document is an annex to the legal bilateral agreement with the implementing partner and constitutes an integral part hereof together with the annex listed in the end of this document.

2. Context, strategic considerations, rationale, and justification

Context analysis

Today's rising generation of 1.8 billion adolescents (aged 10-24) is tomorrow's future. Yet, AGYW face a range of unique outcomes and bear the biggest burden from social and economic inequalities, compared to their male counterparts. For example: one in five young women are married while children; approximately 12 million girls aged 15–19 years give birth each year; girls are 1.5 times more likely than boys to be excluded from primary school; 16% of girls and young women aged 15-24 have experienced sexual violence in the past 12 months. Climate change exacerbates and creates new domains of inequality — making girls more vulnerable to harmful practices such as child marriage, being forced to drop out due to economic insecurity or prioritisation of male siblings, and increased burden of time spent on work like fetching fuel and water. PC works across disciplines and sectors to build a global body of evidence on population and climate issues and generates knowledge on how the climate crisis intersects with ingrained economic and social inequalities. There is tremendous power in investing and intervening during adolescence — a short, critical window in development — to ensure that AGYW can grow into healthy adults, with multiplying benefits to them, their families, and communities. Evidence is needed to guide policies and programs that address the vulnerabilities and opportunities for AGYW as well as to better understand the effects of the investment in AGYW on individual and societal outcomes.

As the HIV epidemic enters its fifth decade, its face is now young and female, particularly in sub-Saharan Africa, where women account for 63% of all new infections, and girls account for nearly 75% of new infections in adolescents. To reverse the epidemic, women and girls will need access to a range of prevention products that align with their preferences and lifestyles. Yet currently available options for HIV prevention and contraception are often unrealistic for many women, who urgently need practical, self-initiated tools they can and are willing to use.

A future where every girl and woman can stay healthy and thrive is possible when their social, structural, and health needs are meet. Implementing evidence-driven development programs and policies to support a safe transition to adulthood and developing discreet, woman-controlled products for protection against HIV and unintended pregnancy are critical pieces in this effort. Together these strategies can meet the needs of girls and women and support their overall health so they can reach their full potential, an important step towards achieving gender equality.

The partner

The Population Council (PC) was founded in 1952 by John D. Rockefeller III and is headquartered in New York. The organisation's core area is medical research into human reproduction, sociological research and support for the design and implementation of national policies and programs in developing countries that give the population access to services within sexual and reproductive health, incl. family planning. PC is considered the leading NGO in SRHR research. In 2022, PC acquired the intellectual property of the International Partnership for Microbicides (IPM), including the dapivirine vaginal ring (DVR) portfolio. This agreement brought together two organisations with aligned missions to accelerate product development and expand global impact, generating benefits from synergies of knowledge, technologies, relationships, and resources, enabling streamlined operations and efficiencies. This acquisition solidifies The Center for Biomedical Research (CBR) position as the leading innovator of high-quality SRH products created with end-user preferences and accessibility in mind.

For 70 years, PC has contributed to global thinking on critical health and development issues through social science, public health, and biomedical research. Through their <u>Strategic plan</u> (see box) they are harnessing their expertise to advance four global goals that reflect the urgent problems the world faces:

Population Councils four global goals 2023-2030

- 1. Ensure sexual and reproductive health, rights, and choices
- 2. Empower adolescents and young people to reach their full potential
- 3. Achieve gender equality and equity
- 4. Pursue justice in the face of climate and environmental changes

The GIRL Center

More than 25 years ago, PC made the case that support to AGYW in the global development agenda is a smart investment to achieve social and economic progress¹. PC has subsequently built the world's largest body of evidence on understanding AGYW's intersecting vulnerabilities, as well as on "what works" (and what does not) vis-à-vis programming to improve AGYW's empowerment, health, education, and economic status. In 2017, the Council established the GIRL (Girl Innovation, Research, and Learning) Center to bring together and amplify the extensive work on AGYW. The GIRL Center focuses on systematically building bodies of evidence across countries, creating user-friendly tools to make data and insights on AGYW more accessible, as well as packaging and communicating the data in ways that drive evidence use and impact. The GIRL Center also leverages its convening power to bring together colleagues across disciplines and expertise to innovate and collaborate. For example, the External Research Collaborator Program is a network of researchers based in LMICs that collectively develops AGYW-focused research agendas, co-creates policy-relevant research activities, and mentor's young researchers.

The GIRL Center is unique in this sector, as they aim to answer questions related to adolescents, with a nuanced understanding of the various dimensions of AGYW's lives, as well as the connections to policy and practice. Advocacy groups are vocal and offer visibility yet need rigorous data that is readily available and easily translatable

¹ Mensch, Barbara S., Bruce, Judith, and Margaret E. Greene. 1998. The Uncharted Passage – Girls' Adolescence in the Developing World. New York: Population Council.

to make their case. Policymakers need and want data, in a relevant format, to drive evidence-based decision-making and inform their investments. Practitioners who implement programs also need data on what works, so they can use approaches that are shown to be effective. Given Population Councils unique combination of specialist knowledge and technical expertise, the GIRL Center aims to bridge the fragmented ecosystem by combining research, programming, and policy on adolescents, with a particular focus intersecting issues affecting AGYW, and making it available and accessible in one place to a full range of stakeholders.

The Center for Biomedical Research

CBR is a global product development partnership that develops and ensures access to new and affordable sexual and reproductive health (SRH) products in LMICs. CBR has one of the most diverse SRH focused product portfolios to enhance safety and choice for individuals in the global market compared to any organisation worldwide. PC is advancing the access and introduction of the DVR, a product designed specifically for women to provide discreet protection against HIV infection over the course of one month. In parallel, they continue to advance the three-month DVR, to provide even longer-acting HIV protection and continue to lower access and delivery burden.

PC is also leveraging their experience with developing contraceptives and the DVR to develop a contraceptive-DVR that will protect women against both HIV and unintended pregnancy. HIV and complications due to unintended pregnancy are among the greatest obstacles to women's health and development, and women in areas with high rates of HIV often have the greatest unmet need for modern contraception. Research suggests that women may be two to four times as likely to acquire HIV during pregnancy and the postpartum period, and that women living with HIV/AIDS may face a higher risk of maternal death than HIV-negative women. In LMICs, where nearly half of all pregnancies are unintended, a lack of access to contraception is a major contributor to maternal and newborn deaths, largely due to complications during pregnancy and childbirth. An estimated 218 million women of reproductive age — one-quarter living in sub-Saharan Africa — have an unmet need for contraceptives that would allow them to space their pregnancies. The contraceptive DVR will be a significant tool to help address both HIV and contraception.

While there are existing and emerging HIV prevention technologies gradually being introduced throughout sub-Saharan Africa, the DVR, three-month DVR, and contraceptive DVR are unique products in the HIV prevention landscape that fill a gap no other product can fill.

- They are long-lasting, and do not require daily administration [(as does oral pre-exposure prophylaxis (PrEP)].
- They are user controlled and easily stored at home, so people who have difficulty accessing clinics on a regular basis can use them without interruption.
- They are acceptable to women in a recent study, 2/3 of women who tried both oral PrEP and the monthly DVR preferred the DVR.

PC receives funding from diverse pool of private and public donors. For this current project other donors include Wellspring Philanthropic Fund, Echidna Giving, Children's Investment Fund Foundation (CIFF), USAIDS, Irish Aid, the European & Developing Countries Clinical Trials Partnership (EDCTP), MSD, Grand Challenges Canada, and Germany.

Lessons learned

Denmark has supported the PC with several contributions in the period from 1998-2023 with a total of 110,400,000 DKK. Through these partnerships, PC has delivered solid results and demonstrated capacity to manage Danish funds. Denmark has used PC's extensive expertise in the fields of research/knowledge on SRHR and how this impacts individual lives, communities and the broader population. PC has demonstrated how they successfully have used their research in advocacy work with the aim of changing policies.

The use of the research and resources provided by PC have not been utilized internally to its full potential. More efforts could be made in using the available data in policy and programming, and ensuring that these are shared with relevant embassies. In the future, this will be done through the Gender Focal Point (GFP) network in the MFA, which consist of colleagues from embassies and the MFA HQ. Through this network relevant resources will be shared and PC will be invited as speakers at relevant GFP meetings.

PC is a global leader in research and programs on how to improve the lives of AGYW in developing countries. PC's clear focus on SRHR issues since its establishment in 1952 has allowed the organization to build a unique research base and be a leader in research on AGYW. Their expertise and presence in a large number of ODA eligible countries (including Bangladesh, Egypt, Ethiopia, Ghana, Kenya, Pakistan, Tanzania, and Uganda) allows PC to work across disciplines in these target countries to identify issues, generate data, and provide evidence-based solutions targeted governments, service delivery organisations, donors, and other relevant stakeholder.

In Senegal a project focused on understand misoprostol knowledge and provision amongst health care providers, pharmacists, and the Ministry of Health. Misoprostol is an alternative option for preventing postpartum haemorrhage, available in an inexpensive tablet form that does not require special conditions for storage, and key to improving maternal health in low- and middle- income countries. Several important achievements were brought about by the study, least of which included a 64 percent increase in the number of pharmacists who stock misoprostol; obtaining commitment from the Ministry of Health to train pharmacists on all essential medicines including misoprostol; and wide dissemination amongst pharmacists on the legal status and correct regimen of misoprostol. In Kenya, PC researchers and partners—the Federation of Women Lawyers, Kenya and the National Nurses Association of Kenya, Midwives' Chapter—examined the extent and causes of disrespectful and abusive care during childbirth and designed and implemented a package of interventions to reduce these behaviours. The interventions were targeted at three levels: policy, health facility, and community. Policy activities include the development of a respectful maternity care (RMC) training guide for providers and communities. This guide adheres to a rights-based approach for facility based childbirth. PC and partners have been engaged in policy dialogue with Kenyan Parliamentarians and efforts to pass a Maternal Health Bill that includes efforts to mitigate D&A.

The Adolescent Data Hub (ADH), an open-access data on adolescents, features more than 750 data sources from 138 countries. User engagements with adolescent-focused researchers showed that there is a higher demand for enhanced user functionality as the repository grows. In response, PC leveraged the MFA funding for 2022 to conceptualize the ADH 2.0. in October 2022 the new site was lunch as part of the Adolescent Atlas for Action (A3) and include an array of new features and functionalities (including validated adolescent-relevant modules, indicator definitions, and code) and a more user-friendly design.

Leveraging the prior investment of the MFA, the grant will provide an annual contribution of DKK 10 million from 2024-2026, in total DKK 30 million. The project enables PC to continue to advance two important bodies of work:

- (1) The GIRL Center's evidence-generation and utilisation activities to inform policies and programmes to meet the multi-faceted needs of adolescent girls and young women (AGYW);
- (2) The Center for Biomedical Research (CBR)'s dapivirine vaginal ring (DVR) portfolio of HIV prevention products that meet the needs and preferences of women throughout their lives.

Support from the MFA will enable the Council to conduct research and develop innovative products and tools, and to convene experts, provide scientific and policy advice, produce accessible evidence, and cultivate future leaders to amplify their impact.

Justification

The project is directly in line with the priorities of Denmark's Development Cooperation, including the aim at placing Denmark at the forefront of international efforts to promote SRHR, including the fight against HIV/AIDS. The project will contribute to the Population Council's and the MFA's mutual goals to secure gender equality, girls' and women's rights, in line with the Danish strategy for development cooperation "The World We Share". In line with the "How-to note on Social Sectors and Social Safety Nets" the partnership with PC will contribute to the institutional capacity building of local and national partners and seek to secure access to SRH services for the most marginalised and vulnerable groups.

The organisation is assessed as well-functioning and generally receives great recognition for its work. PC's efforts are focused on meeting the health needs of the most vulnerable groups in the developing countries and are, among other things, known for its ground-breaking research in the field of HIV/AIDS regarding the sexual behaviour of gay and bisexual men, just as the organisation is known for maintaining other controversial topics on the agenda, e.g. sexual abuse of schoolgirls and street children. PC plays an important role in research, which complements the more practically oriented activities that Denmark supports through the United Nations Population Fund (UNFPA), the International Family Planning Association (IPPF), AmplifyChange, MSI Reproductive Choices, and other SRHR organisations. This project will undergo appraisal before approval, where there will be made an updated assessment of PC.

3. Project Objective

This project aims to advance gender equality by generating cutting-edge, multidisciplinary research and tools; developing innovative SRH products; and systematically building bodies of evidence — and translating them into practical policies and programs — to enhance the bodily autonomy, health, and well-being of adolescent girls and women. Gender equality and SRHR are interlinked. Improving SRHR is an entry points to transform gender discriminatory structures, systems, norms and stereotypes.

4. Theory of change and key assumptions

The outcome of this engagement is to promote gender equality through evidence-based research to gain a better understanding on what programmes and polices related to AGYW have the biggest influence on population dynamics, health and well-being, and the interface with climate change and the development and introduction of safe, affordable, effective microbicides and multi-purpose prevention technologies (MPTs) to women where the need is greatest.

The theory of change seeks to contribute to these outcomes through seven outputs where PC can bring added value, and where positive change can contribute to achieving the objective of the engagement:

- Output 1: Generate high quality, policy-relevant data, evidence, and research on the pressing topics affecting AGYW
- Output 2: Advance accessible, user-friendly evidence tools that summarise the lives and needs of AGYW.

- Output 3: Facilitate knowledge translation to inform evidence-based policies, programs, and investments for AGYW.
- Output 4: Secure monthly DVR regulatory approvals in additional LMICs where there is an identified need for the product and expand the monthly DVR use to additional population segments.
- Output 5: Support for DVR access and market implementation to drive the uptake of DVR as an additional HIV prevention option.
- Output 6: Building upon the monthly DVR, secure approvals and support market introduction of a three-month DVR as an alternative and lower cost option.
- Output 7: Advance development of a multipurpose prevention technology (MPT) dapivirine-contraceptive ring towards regulatory approval and market access.

The project's **theory of change (Figure 1)** posits that the production and dissemination of rigorous research, if used by influential decision makers, can enhance the health and wellbeing of adolescent girls and women. The types of activities that are needed include:

- Delivering accessible and actionable data and evidence,
- Developing and introducing new and improved products and tools, and
- Facilitating knowledge translation to inform smart policies and sound investments.

Inputs Outputs Research Impact Activities **Outcomes** Impact Stronger Facilitate evidence base for Deliver Ideas High knowledge decision making accessible · Research & quality translation Increased evidence digestible, technical Convene Peer-reviewed consideration of More expertise actionable, stakeholders to publications evidence in Funding and timely effective Enhanced engage with Evidence decision making evidence policies. health and Advice research synthesis · Greater Ethical findings Advise and programs, wellbeing briefs consensus on practices. standards strengthen of current • Data solutions Partnerships Safe. capacity for and and future dashboards Expanded options products Compounds effective & evidence use generations Policymaking for women- Foster peer-to-& intellectual affordable decision tools controlled HIV peer learning property for microbicide Viewpoints for · Review policies prevention product products traditional and Increased uptake against development social media evidence of new ideas. approaches and products Greater capacity to use evidence Understand and engage key global and national stakeholders: Smarter technocrats (advisors, tech staff), media, donors, policymakers, investments researchers, advocates, civil society, healthcare providers, and product Better research end-users

Figure 1. Theory of Change

The theory of change suggests that the situation for AGYW can be improved through support via mutually efforts:

- If solid documentation and research on topics that affect the health and wellbeing of AGYW is provided, and contributes to the knowledge and awareness by a broad variety of stakeholders, and
- If contraceptives, microbicides for HIV prevention, and MPT products that enable self-care and address the diverse unmet needs of women and girls across their reproductive lifespan are developed, promoted, and made available and accessible to women and girls, and
- If key decision makers are introduced to and made aware of the research and new products,

- Then decision makers will make more evidence based decisions, programmes, and policies that will improve the health and life of AGYW.

The GIRL Center will generate data, evidence, and insights on topics that affect the health and wellbeing of AGYW through primary and secondary research. They will produce products for different audiences including blogs, program briefs, insights pieces, reports, academic papers, and web-based tools. Recognising that ongoing relationships and conversations with key decision makers are critical to fostering research utilisation, they will regularly engage stakeholders (government, researchers, practitioners, advocates, donors) at global, regional, and country levels to increase their capacity to understand new evidence, infuse evidence in their decision-making, and achieve greater consensus on solutions. Evidence-based and effective policies, programs, practices, and investments will ultimately advance the health and wellbeing of current and future generations of AGYW.

The CBR product development and access activities have the potential to achieve long-term impact by addressing the critical health and well-being of women and girls. Leveraging both in-house scientific capabilities and strong established partner collaborations, the vision is to enhance safety and choice in products that promote SRHR, including novel contraceptives, microbicides for HIV prevention, and MPT products that enable self-care and address the diverse unmet needs of women and girls across their reproductive lifespan. To this end, once a robust suite of preclinical and clinical studies can establish product safety, quality, and efficacy, PC seeks regulatory approval and prepares for access by developing partnerships and conducting awareness-raising, education, and market introduction activities. Over 170 million women currently use a technology developed by PC or a technological descendent.

Key assumptions

The project is dependent on PCs ability to communicate their results to the decision makers and the decision makers interest in this area. PC will employ qualitative discussions with key stakeholders to ensure that they are kept informed and interested in the project result and record concrete examples of how data, research, and evidence has enhanced decision-making and influenced policies, programs, practice, or investments. The monthly DVR is the first discreet, long-acting, HIV-prevention product designed specifically for women. The regulatory strategy utilises the positive opinion issued by the European Medicines Agency (EMA) in combination with WHO prequalification to seek National Medical Regulatory Authority (NMRA) approvals in the countries where the product is needed the most. Successful market introduction of a novel HIV prevention method like the monthly DVR requires extensive collaboration across sectors, including multi-lateral agencies, government, community-based, for-profit, and non-governmental organisations, to help ensure these products reach and are used by the populations that need them most.

5. Summary of the results framework

The project's results framework is summarised below and attached as Annex 3. The project consists of a single project-level objective and impact indicator, and discrete outcomes and indicators for the two work streams this engagement encompasses: related to the GIRL Center's AGYW work and CBR's SRHR products.

Results Framework

Project	Advancing gender equality through evidence and products that empower adolescent girls and women
Project Objective	Generate cutting-edge, multidisciplinary research and tools; develop innovative sexual and reproductive health
	products; and systematically build bodies of evidence to enhance the health and well-being of adolescent girls
	and women
Impact Indicator	More effective policies, programs, practices, and products for adolescent girls and women

Outcome 1	The project contributes to the achievement of the SDG5 with an overall strategic goal of promoting gender
	equality through evidence-based research to gain a better understanding on what programmes and polices

		related to AGYW have the biggest influence on population dynamics, health and well-being, and the interface			
		with climate change.			
Outcome	1 indicator	Number of glob	Number of global or national policies, strategic plans, and/or guidelines influenced by the evidence and tools		
		generated by this development engagement			
Baselin	Year	March 2024	Substantial gaps in actionable evidence and tools needed by policy makers to make effective		
e			and strategic investments		
Target	Year	December	Four policies, strategic plans, and/or guidelines influenced by the evidence and tools		
		2026	generated by this development engagement (recognising the risks laid out in Annex 5)		

Output 1	.1	Generate high AGYW	Generate high quality, policy-relevant data, evidence, and research on the pressing topics affecting AGYW		
Output in	dicator	Number of	Number of papers or reports completed/submitted to a journal		
		Number of	evidence briefs published		
Baseline	Year	March 2024	0 papers or reports completed/submitted to a journal		
			0 evidence briefs published		
Target	Year 1	By Dec 2024	2 papers or reports completed/submitted to a journal		
			2 evidence briefs published		
Target	Year 2	By Dec 2025	3 papers or reports completed/submitted to a journal		
			4 evidence briefs published		
Target	Year 3	By Dec 2026	4 papers or reports completed/submitted to a journal		
			5 evidence briefs published		

Output 1	.2	Advance accessible, user-friendly evidence tools that summarise the lives and needs of AGYW		
Output in	dicator	Number of Adolescent Atlas for Action (A3) dashboards added		
		Number of datasets added to the Adolescent Data Hub (ADH)		
Baseline	Year	March 2024	• 0 dashboards added to the A3	
			• 0 datasets added to the ADH	
Target	Year 1	By Dec 2024	• 1 dashboard added to the A3	
			• 10 datasets added to the ADH	
Target	Year 2	By Dec 2025	• 1 dashboard added to the A3	
			• 20 datasets added to the ADH	
Target	Year 3	By Dec 2026	• 2 dashboards added to the A3	
			• 30 datasets added to the ADH	

Output 1.3	3	Facilitate know	vledge translation to inform evidence-based policies, programs, and investments for
Output inc	licator	Number of events/webinars/briefings held with stakeholders	
		Number of	downloads or views of papers, reports, and evidence briefs
			f decision-makers who use our data, research, or evidence in policy, programmatic, or
Baseline	Year	March 2024	0 event/webinar/briefing held with stakeholders
			0 downloads or views of papers, reports, and evidence briefs
			0 decision-makers who use our data, research, or evidence in policy, programmatic, or investment decisions
Target	Year 1	By Dec 2024	5 events/webinars/briefings held with stakeholders
			100 downloads or views of papers, reports, and evidence briefs
			2 decision-makers who use our data and evidence in policy, programmatic, or investment decisions
Target	Year 2	By Dec 2025	10 events/webinars/briefings held with stakeholders
			200 downloads or views of papers, reports, and evidence briefs
			4 decision-makers who use our data and evidence in policy, programmatic, or investment decisions
Target	Year 3	By Dec 2026	15 events/webinars/briefings held with stakeholders
			300 downloads or views of papers, reports, and evidence briefs
			5 decision-makers who use our data and evidence in policy, programmatic, or investment decisions

Outcome 2	Safe, affordable, effective microbicides and MPTs available to women where the need is greatest		
Outcome indicator 2	Number of microbicide and MPT products available in low- and middle-income countries		

Baseline	Year	March 2024	1 product (monthly dapivirine vaginal ring [DVR])
Target	Year	December 2026	2 products (monthly DVR and three-month DVR)

Output 2.1		Secure monthly DVR regulatory approvals in additional LMICs where there is an identified need for			
•			the product and expanding the monthly DVR use to additional population segments		
Output indi	cator	9 new regulatory	y approvals (and/or import permits) obtained from National Medicines Regulatory Agencies		
	•		tified LMICs. All approvals maintained.		
Baseline	Year	March 2024 8 NMRA approvals and 2 import licenses obtained (10 total)			
Target	Year 1	Dec 2024	24 3 additional approvals/import licenses secured (13 total)		
Target	Year 2	Dec 2025	additional approvals/import licenses secured (16 total)		
Target	Year 3	Dec 2026	3 additional approvals/import licenses secured (19 total approvals at end of the award)		

Output 2.2 Support for DVR access and market implementation to drive the uptake of DVR as an addi			R access and market implementation to drive the uptake of DVR as an additional HIV		
		prevention opti	on		
Output indi	cator	Provide technica	al expertise/assistance to country ministries of health (MOH) and other stakeholders (such as		
		healthcare provi	healthcare providers, implementation partners, and procurers) to support initiation and conduct of DVR		
		implementation studies and related market introduction activities			
Baseline	Year	March 2024 14 implementation projects initiated			
Target	Year 1	Dec 2024 2 additional implementation projects initiated (16 total)			
Target	Year 2	Dec 2025 2 additional implementation projects initiated (18 total)			
Target	Year 3	Dec 2026	2 additional implementation projects initiated (20 total by the end of the award)		

Output 2.3 Building upon the monthly DVR, secure approvals, and support market introduction of a			the monthly DVR, secure approvals, and support market introduction of a three-month		
DVR as an alternative and lower cost option					
Output indi	cator	Implement a cli	Implement a clinical bioavailability clinical trial along with supportive product development studies required		
•		for stringent reg	ngent regulatory and country NMRA approvals. Secure at least 1 regulatory approval		
Baseline	Year	March 2024	March 2024 1 clinical trial ongoing		
Target	Year 1	Dec 2024	Dec 2024 1 clinical study report completed		
Target	Year 2	Dec 2025	ec 2025 1 regulatory dossier under review		
Target	Year 3	Dec 2026	1 regulatory approval		

Output 2.4	Output 2.4 Advance development of a multipurpose prevention technology (MPT) dapivirine-cont				
towards regulatory approval and market access			tory approval and market access		
Output indi	cator	Implement a cli	Implement a clinical trial program along with supportive product development studies required for stringent		
		regulatory autho	regulatory authority approval		
Baseline	Year	March 2024 1 clinical trial ongoing (Phase I)			
Target	Year 1	Dec 2024 1 clinical study report complete (Phase I)			
Target	Year 2	Dec 2025	2 clinical trials ongoing (HIV bioavailability and Phase II/III contraceptive efficacy)		
Target	Year 3	Dec 2026	1 clinical trial clinical study report complete (HIV bioavailability)		
			1 clinical trial ongoing (Phase II/III contraceptive efficacy)		

6. Inputs/budget

Danish contribution in DKK	2024	2025	2026	Total
Outcome 1: GIRL Center				
Output 1.1	2,184,545	1,904,553	1,976,004	6,065,102
Output 1.2	1,340,096	1,452,799	1,368,233	4,161,128
Output 1.3	1,475,359	1,642,648	1,655,763	4,773,769
Subtotal	5,000,000	5,000,000	5,000,0000	15,000,000
	1			
Outcome 2: CBR				
Output 2.1	1,337,840	1,857,309	1,905,635	5,100,784
Output 2.2	1,473,018	2,045,620	2,101,861	5,620,499
Output 2.3	674,208	915,145	944,357	2,533,710
Output 2.4	454,958	633,368	656,683	1,745,008
Subtotal	3,940,023	5,451,442	5,608,535	15,000,000

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The total budget for the project for the 34 months is USD \$30,881,184 corresponding to approximately DKK 209,425,234 out of which Denmark will finance DKK 30 million (depending on parliamentarian approval of the Financial act 2024 and 2025). Budget information is included in Annex 5 and summarised below:

Total cost	MFA funding	Other funding (amount and source)
		,
16,072,257	5,668,320	1,882,381 – Wellspring Philanthropic Fund (secured) 1,547,393 – Council Contribution (secured) 4,715,307 – Echidna Giving (secured) 2,258,857 – CIFF (anticipated)
14,292,842	3,888,905	1,882,381 – Wellspring Philanthropic Fund (secured) 1,547,393 – Council Contribution (secured) 4,715,307 – Echidna Giving (secured) 2,258,857 – CIFF (anticipated)
14,865,404	4,461,467	1,882,381 – Wellspring Philanthropic Fund (secured) 1,547,393 – Council Contribution (secured) 4,715,307 – Echidna Giving (secured) 2,258,857 – CIFF (anticipated)
4,966,753	981,308	
50,197,256	15,000,000	
11,778,844	4,767,088	6,165,507 - USAID LEADING (secured) 846,250 – Irish Aid (anticipated)
27,984,363	5,252,803	2,653,766 – USAID LEADING (secured) 15,159,892 – EDCTP (anticipated) 1,840,702 – MSD (anticipated) 2,230,950 – Grand Challenges Canada (anticipated) 846,250 – Irish Aid (anticipated)
30,656,201	2,367,953	22,769,101 – Germany (secured) 4,672,897 – Denmark (secured) 846,250 – Irish Aid (anticipated)
48,064,098	1,630,848	15,536,128 – Germany (secured) 30,050,872 – USAID MATRIX (anticipated) 846,250 – Irish Aid (anticipated)
40,448,046	981,308	, ,
,,	- 1~ ~ ~ 1~ ~ ~	
	16,072,257 14,292,842 14,865,404 4,966,753 50,197,256 11,778,844 27,984,363 30,656,201	16,072,257 5,668,320 14,292,842 3,888,905 14,865,404 4,461,467 4,966,753 981,308 50,197,256 15,000,000 11,778,844 4,767,088 27,984,363 5,252,803 30,656,201 2,367,953 48,064,098 1,630,848 40,448,046 981,308

Beyond the limits defined in the Financial Management Guideline, funds cannot be transferred between the budget lines without prior approval from the Department for Migration, Stabilisation and Fragility. Expenditures beyond the total grant cannot be reimbursed to the Population Council.

7. Institutional and Management Arrangement

This project will be managed by two of the Population Council's flagship Innovation Hubs:

1. The AGYW portfolio is an integral part of the GIRL Center — a global research hub that generates innovative research and catalyses evidence-based change. <u>Dr. Karen Austrian</u>, Director of the GIRL

- Center, will provide technical leadership, quality assurance, and managerial oversight; monitor progress; and serve as the primary point of contact to the MFA.
- 2. The DVR portfolio, acquired by PC from IPM in 2022, has been integrated into CBR. <u>Dr. Brid Devlin</u>, Chief Scientific Officer for CBR, <u>Mr. Willem Kriel</u>, Chief Operating Officer of IPM South Africa (a PC affiliate), and <u>Mr. Leonard Solai</u>, Vice President, Global Product Access and External Affairs of IPM South Africa will provide technical leadership, quality assurance, managerial oversight for all areas of work related to this portfolio. To ensure streamlined communication with the MFA, Stephanie Ecker, Associate Director Grants Management, CBR will remain the primary point of contact.

All project activities will be subjected to the PC's standard quality assurance procedures, which include mechanisms for ensuring high quality and ethically sound standards for both social science and biomedical research.

Monitoring

PC will submit annual narrative and financial reports to the MFA. Quarterly meetings will be used to share progress; discuss learning, challenges, and potential adaptation; and identify new opportunities to engage with Danish actors.

The Ministry of Foreign Affairs of Denmark shall have the right to carry out any technical or financial supervision mission that is considered necessary to monitor the implementation of the project/programme. After the termination of the project/programme support, the Ministry of Foreign Affairs of Denmark reserves the right to carry out evaluations in accordance with this article.

Anti-Corruption and Respecting Danish Red Lines

PC implements a set of policies to prevent and mitigate corruption, and to protect their staff and the populations tehy serve. Staff are required to observe a code of conduct that includes policies on fraud and other corrupt practices; anti-trafficking of persons; bullying; child protection; confidentiality of personnel information; conflicts of interest; discrimination, harassment, and retaliation; illegal use of controlled substances; misconduct in science; safeguarding; solicitations; and whistle blowing.

Other measures to prevent and mitigate corruption include:

- 1. stringent financial management for thorough monthly review of all expenses and financial transactions;
- 2. annual 'ethics training' for all staff that includes anti-bribery and corruption rules as well as conflict of interest guidelines;
- 3. due diligence and monitoring for partners;
- 4. procurement policies that ensure transparency and segregation of responsibilities;
- 5. an enterprise resource planning system to monitor unusual trends at project, country, and headquarters levels;
- 6. signing authority matrix to ensure segregation of duties and verification/approval by relevant staff for all types of payments;
- 7. subcontracts with partners that require compliance with their anti-bribery and corruption procedures.

Communicating Results

A communication plan is provided in Annex 6. Key messages will concentrate around the evidence base behind and how investing in AGYW and SRH product development will support the UN SDGs and Denmark's priorities for development cooperation including in relation to the health and rights of girls and women. Key audiences include community stakeholders, civil society and advocacy groups, national governments, implementers, multilateral agencies and regional groupings, international and national NGOs, researchers, and donors.

The Population Council's Office of Strategic Communications will ensure that results are communicated clearly and persuasively in a variety of fora, including presence at international and national meetings and conferences. Results will be disseminated via peer-reviewed publications, guidelines, programmatic, policy and research briefs, as well as via the Population Council's channels including website, newsletters, social media presence, and webinars.

8. Financial Management, Planning, and Reporting

PC will submit the following annual reports:

- 1) Annual report and audited financial statements, specifying the Danish contribution as income
- 2) Updated budget overview (the use of funds and expected allocation of funds between outcomes and output for the coming year).

Narrative progress reports and financial reports

Reporting period	Due date	Reports due
1 March 2024 – 31 Dec	30 April 2025	Reporting documents as described in points 1-2 above
2024		
1 Jan 2025 – 31 Dec 2025	30 April 2026	Reporting documents as described in points 1-2 above
1 Jan 2026 – 31 Dec 2026	30 April 2027	Reporting documents as described in points 1 above

Accounting and auditing: Both parties will strive for full alignment of the Danish support to the implementing partner rules and procedures, while respecting sound international principles for financial management and reporting. The audit will only include the Danish support or the total project.

Procedures and minimum requirements pertaining to disbursements

Period	Payment	Estimated	Contingent upon
	amount	date	
1 March 2024 – 31 Dec	10,000,000 DKK	March 2024	-Signature of agreement
2024			
1 Jan 2025 – 31 Dec 2025	10,000,000 DKK	April 2025	- Receipt of 2024 annual report, audited
			financial statements
			- Updated budget overview
1 Jan 2026 – 31 Dec 2026	10,000,000 DKK	April 2026	Receipt of 2025 AC annual report, audited
			financial statements

Immediately after receiving a payment PC must forward a receipt to the Danish Ministry of Foreign Affairs.

Financial management of the project will follow Population Council's procedures and be integrated into their financial management system to ensure financial accountability, and that outputs are met, and each project achieves value for money. The Office of the Chief Financial Officer (CFO) provides financial, budgetary, and accounting support and oversight, including preparation and submission of donor financial reports, ensuring compliance with donor regulations and adherence to financial management standards. Project staff are responsible for financial monitoring and oversight of grant expenditure against budget. PC provides financial monitoring and oversight tools to help project staff assess grant expenditure rates against budget. Expenditure reports, analyses, and updates are prepared monthly and posted on the Population Council's Intranet to provide transparency and allow proper and timely oversight of activities.

The Population Council's Global Procurement Manual, reviewed annually, sets forth global policies and procedures for the purchase of all goods and services necessary for administering operations and implementing programs in accordance with international standards.

The Population Council's internal control follows an annual internal audit plan based on the risk assessment that examines high-risk environments and adherence to financial policies, procedures, and industry best practices. The organisation's internal audit of its offices is performed by external auditors who report their findings to the Board of Trustees' Audit Committee. International offices' statutory audits are performed by locally contracted audit firms. The annual external audit of the financial statements, audit of federal awards, funder specific audit requirements, and US Internal Revenue Service reporting was previously performed by KPMG and is currently performed by Grant Thornton, under contract since 2020, reporting to the Board of Trustees' Audit Committee.

9. Risk Management

A detailed Risk Management Matrix is provided in Annex 4, building on the Population Council's risk management framework. Overall, the main contextual risk to the success of this project is that use of product outputs is contingent on continued political commitment and funding to addressing SRHR and gender equality. Through ongoing engagement with a variety of stakeholders (detailed in Annex 1 – Context Analysis), PC will work to secure buy-in and that evidence and products respond to needs. Programmatic risks generally relate to quality of the outputs, and challenges in the development and introduction of biomedical products. The Population Council's rigorous quality assurance processes and engagement of end-users and other key actors will mitigate these risks. Finally, sound financial management systems and human resources policies will mitigate institutional risks. PC will communicate any risks that manifest and planned response via regular dialogue with MFA and summarise these in annual reporting.

PC employs a system of Enterprise Risk Management (ERM) through which they proactively and continually identify, assess, manage, and monitor the risks associated with the conduct of research and operational activities. PC ERM procedures include five steps: (1) risk identification; (2) risk analysis; (3) risk oversight; (4) risk mitigation; and (5) risk monitoring and review.

PC undertakes a comprehensive, cross-disciplinary approach to risk management through its Risk Review Group (RRG), headed by the Population Council's Legal Counsel and comprising senior staff from across the organisation. The RRG meets regularly to assess potential new risks and develop measures to manage those already identified and provides training and support on ERM to PC staff.

10. Closure

Three months prior to the project's end date, PC will initiate closeout procedures, including preparation of the final narrative and financial reports, and convening of a closeout meeting with the MFA.

Annexes:

Annex 1: Context Analysis

Annex 2: Partner Assessment

Annex 3: Theory of Change and Result Framework

Annex 4: Risk Management

Annex 5: Budget Details

Annex 7: Plan for Communication of Results

Annex 8: Process Action Plan

Annex 9: Quality Assurance Checklist or signed table of appraisal recommendations and follow-up actions taken, depending on whether the appraisal has been conducted by a development specialist

Poverty and Inequality Analysis

The 21st century has and continues to see dramatic social, political, and demographic changes. Increasing population growth, younger age, and shifting household structures, deepening inequities in educational and health outcomes, and increasing urbanization are hindering progress made in health and development. The COVID-19, climate, and humanitarian crises are laying bare and exacerbating gender, economic, and social inequalities. These intersecting problems are disproportionately impacting populations and communities that have been systematically underserved, driving them into further marginalization and deeper poverty. Those with historic power and privilege have been less impacted, consolidating and enhancing their social and economic advantages, leading to increasing inequality within and between populations around the world.

This development engagement directly addresses gender inequalities, with a specific focus on:

- 1. Empowering adolescent girls and young women (AGYW) by advancing evidence-informed policies and programs that meet their multi-faceted needs; and
- 2. Promoting sexual and reproductive health and rights (SRHR) by developing and ensuring access to safe and effective HIV and pregnancy prevention products.

Adolescent Girls and Young Women (AGYW)

Today's rising generation of 1.8 billion adolescents (ages 10-24) are tomorrow's future. Yet, AGYW face a range of unique outcomes and bear the biggest burden from social and economic inequalities, compared to their male counterparts. For example:

- One in five young women are married while children.
- Approximately 12 million girls aged 15–19 years and at least 777,000 girls under 15 years give birth each year.
- Complications in pregnancy and childbirth are the leading cause of death among girls aged 15 to 19 worldwide.
- Girls are 1.5 times more likely than boys to be excluded from primary school.
- In low-income countries, less than two thirds of girls complete their primary education, and only one in three completes lower secondary school.
- Sixteen percent of girls and young women aged 15-24 have experienced sexual violence in the past 12 months.
- Around 200 million girls and women living in over 30 countries have experienced female genital mutilation and cutting (FGM/C).

The implications of these experiences for girls in adolescence – school dropout, early marriage, motherhood, sexual and gender-based violence – can perpetuate cycles of poverty, poor health, and development outcomes.

Although adolescents in Africa were mostly spared from the direct effects of the COVID-19 pandemic on their health, there are numerous lingering effects on their wellbeing stemming from disrupted access to health and education services and prolonged periods of social isolation and exclusion, setting back many gains of the previous decades. Coupled with the climate crisis, a lurking debt crisis, limited economic opportunities, and rising food and energy prices, a successful transition to adulthood is increasingly difficult.

Sexual and reproductive health and rights (SRHR)

Women, men, and young people around the world have the right to decide freely whether, when, and

how many children they have. They have the right to access the information, services and supplies they need to achieve their reproductive health intentions and prevent sexually transmitted infections (STIs). Yet, for millions of people, particularly the poorest and most marginalized populations, these rights are not being realized – with vast unmet need for high quality, voluntary, and rights-based information and services including for HIV/STI prevention, contraception, safe abortion, maternal and newborn health, sexuality education, and many other areas under the comprehensive and integrated definition of SRHR. Worryingly, the SRHR of people around the world are under increasing threat from ideologically driven forces seeking to roll-back hard-won gains, slash funding for life-saving services, and remove references to SRHR from international agreements.

The high cost of addressing HIV/AIDS and other serious illnesses can drive families to financial ruin, trapping them in a cycle of poverty and weakening economies. The United Nations 2030 Sustainable Development Goals (SDGs) include a target of ending AIDS by 2030, and reducing the number of HIV infections can impact illness-related poverty and keep families and communities strong.

The HIV epidemic's disproportionate impact on women stems from two primary causes: 1) women are biologically more likely than men to become infected with HIV during vaginal intercourse and 2) women face persistent gender inequities and power imbalances in relationships and during sexual encounters. In some parts of sub-Saharan Africa, HIV is as much as eight times more prevalent in AGYW than in young men, partly because they lack effective and discreet prevention tools they can use on their own, without partner negotiation. Young women are the most vulnerable, at least twice as likely to become infected with HIV as their male peers. In Africa, girls account for nearly three of every four new infections in adolescents. Currently available options for HIV prevention are often unrealistic for many women, who urgently need practical, self-initiated tools they can and are willing to use.

HIV/AIDS and maternal mortality, and their frequent intersection, are among the greatest obstacles to women's health and development. Together, they constitute the two leading causes of death among women of reproductive age and underscore the urgent need for new tools women can use to safeguard their health. Growing evidence indicates that women may be more apt to use an HIV prevention method if it also prevents pregnancy, i.e., a multipurpose prevention technology (MPT). Currently, the only available method for preventing both HIV and unplanned pregnancy is condoms. Male condoms, however, are not under a woman's control, and cultural norms and gender-based violence block many women's ability to negotiate condom use. Female condoms have had limited uptake due to cost, access, and acceptability issues (including male partners' objections). MPTs that meet the dual prevention needs of women and girls are likely to enhance product uptake and effective use, and have broad-based impact on SRHR outcomes.

Political Economy and Stakeholder Analysis

In addition to aligning with Danish development priorities (see "Matching with Danish Strengths and Interests," below), this development engagement aligns with the priorities of the EU and other Member States including a direct focus on: Africa, human development, economic development, and climate change; through these, it will also address issues in relation to migration and peace and stability.

Importantly, this work directly aligns with expressed priorities of the African Union (AU) and its Member States most notably the AU roadmap on "Harnessing the Demographic Dividend through Investments in Youth", which was adopted in January 2017. African countries have begun to prepare national roadmaps for the investments in youth required to realize the demographic dividend, and the research outputs from this development engagement will speak directly to the issues that will be relevant to their progress.

This project will also make a direct contribution to the Development Effectiveness agenda by:

- enhancing the body of research and evidence on the policies, programs, and interventions to improve outcomes for AGYW.
- advancing the development and availability of HIV-prevention and MPT products to offer a range of discreet, women-controlled, methods to protect their SRHR on their own terms.

The Population Council recognizes that change will not occur unless research and evidence, and their implications for policies and programs, are effectively communicated to a range of key local to global stakeholders. Priority audiences for this engagement include:

- Community stakeholders to foster a supportive environment for research and product uptake. This includes policy maker advocacy and outreach, training of community leadership (traditional leaders and traditional healers), and educational activities for adolescent girls and young women.
- Civil society and advocacy partners at global, regional, national, and community levels to ensure issues such as AGYW empowerment, SRHR, and poverty-related diseases and global health are key policy priorities.
- National governments in target countries and OECD Development Assistance Committee countries who are making decisions about national HIV/AIDS prevention and SRHR policies, national adolescent health, education, social protection programs, policies, and budgets.
- Multilateral agencies including the WHO, Global Fund, UN and World Bank, and regional groupings such as the AU and EU who can use evidence on adolescent vulnerability, SRHR technologies, and what works (and does not) to shape their advocacy, program and procurement, and policy/guidance.
- International and national NGOs that can use data and evidence to better design and target their programming.
- Global research and development partners who can use data and evidence to advance future health and development research and evidence generation.

It is widely acknowledged that fragility most negatively affects the poorest and the most vulnerable groups in society, including women and children. A 2017 report¹ by the OECD noted that "around the world, conflict, fragility and gender inequalities erode peoples' opportunities to fulfil their potential and undermine our prospects for sustainable development. These challenges also reinforce each other: societal norms that discriminate against women can fuel conflict and violence, and conflict and fragility in turn multiply the burdens faced by women and girls".

A 2022 OECD report² makes the case that women and girls in fragile contexts continue to be more exposed to specific health risks, such as maternal mortality, female genital mutilation, and early pregnancies; tend to have lower educational outcomes, significant impact on the health, cognitive and socio-behavioural development of their children; experience higher levels of gender discrimination, lower access to social protection, worse working conditions and lower pay. These issues compound to hinder their ability to transform their human capital into empowerment. For example, a Population Council study among displaced Rohingya in Cox's Bazaar, Bangladesh found rising rates of child marriage; misconceptions around contraception, HIV, and other STIs; and inaccessibility of reproductive health services for adolescents and youth in camps.³

Evidence also shows that rapid- and slow-onset disasters (both man-made and natural) — including climate and weather-related events, epidemics, and economic crises — disproportionately affect women and girls. The Girls in Emergencies Collaborative was co-founded by the Population Council and the Women's Refugee Committee in recognition of the fact that adolescent girls in fragile and conflict affected settings face a multiplicity of risks during the crisis. The Collaborative has called attention to the fact that, "many adolescent girls, the poorest girls in the poorest communities, already live in an 'emergency'. Humanitarian crises only amplify the call on their coping and caring capacities, while exacerbating their vulnerabilities. For too many girls worldwide, an emergency begins as an 'event' and transforms into a lifetime. Evidence reveals that women and girls not only faces a multiplicity of risks during a crisis, but also because they remain invisible, unprotected, and unengaged, particularly in the crucial first 45 days of a crisis. Despite a plethora of gender guidelines and litany of 'duty bearers,' adolescent girls are left behind in emergencies, just as they have been left behind in conventional development."

Human Rights, Gender, Youth and Applying a Human Rights Based Approach

For many AGYW, the lack of access to SRH services is depriving them of their rights and the ability to make decisions about their bodies and to plan their families. High rates of school drop-out, child marriage, teen pregnancy, and SGBV experienced by AGYW are adversely affecting their education and employment opportunities and risks creating a vicious cycle trapping families and communities in poverty that is reflected in multiple dimensions. The climate crisis is exacerbating the range of challenges AGYW face, including increased disruptions to education and livelihoods, forced migration and pressures to marry.

The consequences of the range of adverse outcomes experienced by millions of AGYW directly impacts their ability to lead healthy and productive lives and to achieve their full potential. At the population level, the lack of progress in ensuring universal access to high-quality and rights-based health and education, including SRH services and comprehensive sexuality education, impacts economic growth, poverty reduction, and the achievement of the SDGs.

¹ OECD (2017) Gender equality and women's empowerment in fragile and conflict affected situations: a review of donor support.

² OECD (2022), "How fragile contexts affect the well-being and potential of women and girls", OECD Development Co-operation Directorate, OECD Publishing, Paris.

³ Ainul, Sigma, Iqbal Ehsan, Eashita F. Haque, Sajeda Amin, Ubaidur Rob, Andrea J. Melnikas, and Joseph Falcone. 2018. "Marriage and Sexual and Reproductive Health of Rohingya Adolescents and Youth in Bangladesh: A Qualitative Study." Population Council: Dhaka, Bangladesh.

⁴ "Statement and Action Agenda from the Girls in Emergencies Collaborative" (2015). Expert Consensus Document. https://annalsofglobalhealth.org/articles/10.1016/j.aogh.2015.08.004

According to the UN Human Rights Office (OHCHR): "Human rights are intimately linked with the spread and impact of HIV/AIDS. A lack of respect for human rights fuels the spread and exacerbates the impact of the disease, while at the same time HIV undermines progress in the realization of human rights. This link is apparent in the disproportionate incidence and spread of the disease among certain groups which, depending on the nature of the epidemic and the prevailing social, legal and economic conditions, include women and children, and particularly those living in poverty." 5

In addition, women and adolescent girls in areas with high rates of HIV often face an unmet need for family planning. In fact, the intersection of HIV and reproductive health poses one of the greatest threats to women's health and rights. HIV/AIDS is a leading cause of death and disability among pregnant women and mothers. Women living with HIV who are pregnant or recently gave birth are eight times more likely to die than those who are HIV-negative. The consequences for children are also enormous: observational studies in sub-Saharan Africa show that children are up to four times more likely to die during the year before or after their mothers died. Expanding the range of HIV prevention options for women would also help give mothers and their newborns a greater chance at healthy futures.

Migration

Migration is an essential element in national social and economic growth. AGYW in low- and middle-income countries are migrating to urban areas in ever greater numbers, because they lack opportunity in their rural hometowns, and want to work, to learn, and to gain skills and resources. They also move to escape hardship: poverty, war, or early marriage.

In a landmark report,⁶ the Population Council highlighted both the risks and benefits of migration for AGYW. Without support, girls can find themselves isolated or in circumstances that are dangerous, abusive, or economically exploitative. Preparing girls before they leave, protecting them along the way, and assisting them where they land can also unlock opportunity, autonomy, and the chance for prosperity.

HIV and migration are also inextricably linked. Particularly in sub-Saharan Africa, HIV has historically followed the paths of populations as they moved around the continent, and migration continues to place individuals at greater risk of HIV acquisition and onward transmission. Adolescent girls and women can also be put an increased risk of HIV when their male partners migrate for seasonal work. In India, for example, the Population Council documented the relationship between spousal outmigration and the HIV serostatus of married women in rural India.⁷

Inclusive Sustainable Growth, Climate Change, and Environment

⁵ www.ohchr.org/en/health/hivaids-and-human-rights

⁶ Temin, Miriam, Mark R. Montgomery, Sarah Engebretsen, and Kathryn M. Barker. 2013. "Girls on the Move: Adolescent Girls & Migration in the Developing World," A Girls Count Report on Adolescent Girls. New York: Population Council.

⁷ Saggurti N, Mahapatra B, Sabarwal S, Ghosh S, Johri A (2012) Male Out-Migration: A Factor for the Spread of HIV Infection among Married Men and Women in Rural India. PLoS ONE 7(9): e43222. https://doi.org/10.1371/journal.pone.0043222

Girls are disproportionately affected by the adverse consequences of climate change, facing a variety of harms that hinder their health, well-being, and potential. Climate change exacerbates existing gender inequalities—and creates new domains of inequality — making girls more vulnerable to harmful practices like child marriage, being forced to drop out due to economic insecurity or prioritization of male siblings, and increased burden of time spent on 'drudge' work like fetching fuel and water. Climate-related disasters also disrupt education for many learners across the world each year, leading to increased school absenteeism and the perpetuation of educational inequalities. In Zambia, for example, the Population Council documented how lower household incomes due to drought in farming communities resulted in young children increasingly entering the workforce, and young girls being married when families could not afford school fees and struggled to support them financially. Without proactive measures and attention in place, the climate crisis threatens to undo progress made to date advancing the education and well-being of adolescent girls particularly in the Global South.

The product development component of this engagement is also mindful of sustainability. Securing approval for and introducing a three-month dapivirine vaginal ring offers several advantages over the one-month ring, including fewer rings to transport, resulting in savings in storage and transportation, decreasing the burden on health systems, and reducing potential environmental impact due to less frequent disposal of used rings.

Matching with Danish Strengths and Interests, Engaging Danish Actors, Seeking Synergies

This development engagement directly aligns with "The World We Share – Denmark's Strategy for Development Cooperation" (2021) in which gender equality and the rights of women and girls are positioned as a crosscutting priority. To this end, the new strategy posits a particular focus on SRHR and promises support for concrete equality and SRHR initiatives locally and during humanitarian crises. In line with the "How-to note on Social Sectors and Social Safety Nets" the partnership with The Population Council will contribute to the institutional capacity building of local and national partners and seek to secure access to SRH services for the most marginalised and vulnerable groups.

The Population Council recently launched a <u>2023-2030 Strategic Plan</u>, through which we are harnessing our expertise to advance **four global goals** that reflect the urgent problems the world faces, and contribute to the SDGs:

- 1. Ensure sexual and reproductive health, rights, and choices
- 2. Empower adolescents and young people to reach their full potential
- **3.** Achieve gender equality and equity
- **4.** Pursue justice in the face of climate and environmental changes

The Population Council has a longstanding collaboration with AIDS Fondet and will continue to explore synergies and involve Danish officials, cooperation partners, private and civil society actors, and the general public to generate awareness of their work, and interest in international development more broadly, and elicit input to further guide the project outputs. For example, The Population Council could provide training to Danish Embassies on the application of their tools to inform data-driven policies and programs for AGYW, and/or a technical briefing on mainstreaming climate considerations into development programs.

⁸ Rosen, J.G., Mulenga, D., Phiri, L. et al. "Burnt by the scorching sun": climate-induced livelihood transformations, reproductive health, and fertility trajectories in drought-affected communities of Zambia. BMC Public Health 21, 1501 (2021). https://doi.org/10.1186/s12889-021-11560-8

Annex 2: Partner assessment About Population Council

The Population Council is an international, non-governmental research organisation headquartered in the US, with a network of international offices and independent affiliated organizations in 13 countries around the world. An international Board of Trustees, which includes leaders in sexual and reproductive health (SRH), biomedical research, education, climate change, communications, international law, finance, investment, and management, oversees and guides the Population Council.

Denmark has supported the Population Council with several contributions in the period from 1998-2015 and again from 2020-2023. Through these partnerships, the Population Council has delivered solid results and demonstrated capacity to manage Danish funds. Since 2015, Danish development officials have continued to have dialogue with the Population Council due to the extensive expertise offered by the Population Council in the fields of research/knowledge on sexual and reproductive health and rights and how this impact on individual lives and at the community and population levels.

The Population Council brings unique multidisciplinary expertise in biomedical, social science, and public health research, including population dynamics and climate change, demography, economics, epidemiology, geography, and political science. The Population Council has a global workforce of around 400 staff with offices in Bangladesh, Egypt, Ethiopia, Ghana, Guatemala, India, Kenya, Mexico, Nigeria, Pakistan, Senegal, South Africa, and Zambia. These international offices are almost exclusively staffed by professionals from those countries, and support work in more than 30 countries globally. Through this on-the-ground presence, the Population Council works across disciplines and at the global, national, and local levels to identify issues, generate data, provide evidence-based solutions, and enable governments, service delivery organisations, donors, and other relevant stakeholders to increase impact.

The Girl Innovation, Research, and Learning (GIRL) Center, Population Council

More than 25 years ago, the Population Council was among the first to make the case that support to adolescent girls and young women (AGYW) in the global development agenda is a smart investment to achieve social and economic progress. The Council has subsequently built the world's largest body of evidence on understanding AGYW's intersecting vulnerabilities, as well as on "what works" (and what does not) vis-à-vis programming to improve AGYW's empowerment, health, education, and economic status.

In 2017, the Council established the GIRL Center to bring together and amplify its extensive work on AGYW. The GIRL Center focuses on systematically building bodies of evidence across countries, creating user-friendly tools to make data and insights on AGYW more accessible, as well as packaging and communicating the data in ways that drive evidence use and impact. For example, the GIRL Center's Adolescent Data Hub is the world's largest catalog of open-access data on adolescents, the ADH features more than 750 data sources from 138 countries. The Adolescent Atlas for Action (A3), co-funded by the Danish MFA, is a suite of web-based dashboards that provides a multidimensional perspective on adolescent lives and experiences in LMICs. The A3 aims to arm adolescent-focused stakeholders with evidence and data to inform policies, programs, and investments.

The GIRL Center also leverages its convening power to bring together colleagues across disciplines and expertise to innovate and collaborate. For example, its External Research Collaborator Program is a network of researchers based in LMICs that collectively develops AGYW-focused research agendas, co-creates policy-relevant research activities, and mentors young researchers.

The Center for Biomedical Research, Population Council

Through its Center for Biomedical Research, the Population Council has developed and licensed some of the most widely used long-acting, reversible contraceptives in the world. The Population Council collaborates with pharmaceutical companies to develop, manufacture, and distribute contraceptives and other products to the global market. In keeping with the Council's mission, these partnerships include provisions to ensure that products are offered to people in LMICs at public-sector prices.

In 2022, the Population Council acquired the intellectual property of the International Partnership for Microbicides (IPM), including the dapivirine vaginal ring (DVR) portfolio. This agreement brought together organizations with aligned missions to accelerate product development and expand global impact, generating benefits from synergies of knowledge, technologies, relationships, and resources, enabling streamlined operations and efficiencies.

The monthly DVR is the approved first long-acting HIV prevention method designed for women. Made of flexible silicone, the ring slowly releases the antiretroviral drug dapivirine in the vagina. Women insert the product and replace it every month. In 2020, the monthly DVR received a positive European Medicines Agency (EMA) opinion for its use in developing countries and a World health Organization (WHO) recommendation. Regulatory agencies in nine African countries subsequently approved the ring for distribution. Currently, additional regulatory reviews remain ongoing in Africa and DVR introduction activities are underway.

The successful development of the monthly DVR has now opened the door to development of followon products including the three-month DVR, which would lower annual costs, and a three-month dapivirine-contraceptive vaginal ring, a multipurpose prevention technology (MPT), designed to simultaneously meet two major SRHR needs by reducing HIV risk and preventing unintended pregnancy.

With over six decades of combined experience developing products created with end-user preferences and accessibility in mind, the Centre for Biomedical Research has one of the most diverse SRH focused product portfolios of any organization worldwide.

1. Summary of key partner features

Partner	Core	Importance	Influence	Contribution	Capacity	Exit
name What is the name of the partner?	business What is the main business, interest and goal of the partner?	How important is the programme for the partner's activity-level (Low, medium high)?	How much influence does the partner have over the programme (low, medium, high)?	What will be the partner's main contribution?	What are the main issues emerging from the assessment of the partner's capacity?	strategy What is the strategy for exiting the partnership?
Population	Research in	Medium. The	High. The	The	Strong	The
Council	population,	Population	Population	Population	capacity	Population
	health, and	Council has a	Council	Council is	with	has a
	development,	diversified	will	the only	expertise	diversified
	including in	donor base	manage	partner thus	in the	donor base
	the fields of	with	the	contributing	particular	and will be
	AGYW and	governmental	delivery of	all results,	research	able to
	biomedical	and private	project	including	agendas	continue
	research	donors. The	outputs.	activities	addressed	operations
		project will			by the	and

enable the	previously	project,	activities
Population	led by IPM.	including	building on
Council to	-	with the	the project
further build		acquisition	results
on other		of the	following
activities to		IPM-	end of the
maximize		related	project.
impact		activities.	
especially in			
the fields of			
AGYW			
wellbeing and			
HIV-			
prevention			
and			
biomedical			
research			

ANNEX 3: THEORY OF CHANGE AND RESULTS FRAMEWORK

The Population Council's (PC) unique combination of social science, public health, and biomedical research enables us to take a multidisciplinary approach to the world's most urgent development challenges. PC leverages their global talent, local presence, and expertise to conduct research and develop innovative products and tools across their research portfolios. PC amplifies their impact by convening experts, providing scientific and policy advice, producing accessible evidence, and cultivating future leaders.

The project's **theory of change (Figure 1)** shows that the production and dissemination of rigorous research, if used by influential decision makers, can enhance the health and wellbeing of underserved populations. The types of activities that are needed include:

- Delivering accessible and actionable data and evidence,
- Developing and introducing new and improved products and tools, and
- Facilitating knowledge translation to inform smart policies and sound investments

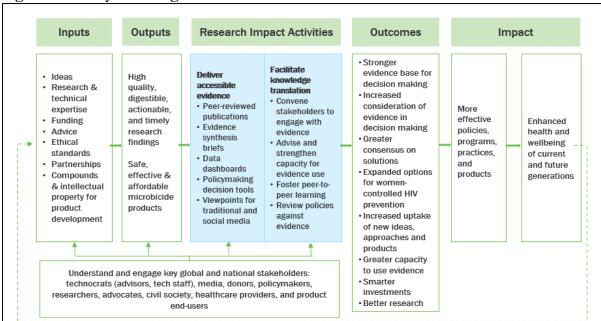


Figure 1. Theory of Change

The GIRL Center will generate data, evidence, and insights on topics that affect the health and wellbeing of AGYW through primary and secondary research. PC will produce products for different audiences including blogs, program briefs, insights pieces, reports, academic papers, and web-based tools. Recognising that ongoing relationships and conversations with key decision makers are critical to fostering research utilisation, PC will regularly engage stakeholders (government, researchers, practitioners, advocates, donors) at global, regional, and country levels to increase their knowledge on new evidence, infuse evidence in their decision-making, and achieve greater consensus on solutions. Evidence-based and effective policies, programs, practices, and investments will ultimately advance the health and wellbeing of current and future generations of AGYW.

PCs biomedical product development and access activities have the potential to achieve long-term impact by addressing the critical health and well-being of women and girls. Leveraging both in-

house scientific capabilities and strong established partner collaborations, PC's vision is to enhance safety and choice in products that promote SRHR, including novel contraceptives, microbicides for HIV prevention and multi-purpose prevention technology (MPT) products that address the diverse needs of women and girls across their reproductive lifespan. To this end, once a robust suite of preclinical and clinical studies can establish product safety, quality, and efficacy, PC seeks regulatory approval and prepares for access by developing partnerships and conducting awareness-raising, education, and market introduction activities.

The Results Framework is presented on the following pages, with a single project-level objective and impact indicator, and discrete outcomes and indicators for the two workstreams this engagement encompasses: related to AGYW and SRHR products.

Results Framework

Project	Advancing gender equality through evidence and products that empower adolescent girls and women
Project Objective	Generate cutting-edge, multidisciplinary research and tools; develop innovative sexual and reproductive health products; and systematically build bodies of evidence to enhance the health and well-being of adolescent girls and women
Impact Indicator	More effective policies, programs, practices, and products for adolescent girls and women

Workstream 1: AGYW

Outcome 1 The project contributes to the achievement of the SDG5 with an overall strategic goal of promoting equality through evidence-based research to gain a better understanding on what programmes and polices to AGYW have the biggest influence on population dynamics, health and well-being, and the interface with change.				
Outcome	1 indicator		or national policies, strategic plans, and/or guidelines influenced by the evidence and tools levelopment engagement	
Baseline	Year	March 2024 Substantial gaps in actionable evidence and tools needed by policy makers to make effective and strategic investments		
Target	Year	December 2026	Four policies, strategic plans, and/or guidelines influenced by the evidence and tools generated by this development engagement (recognising the risks laid out in Annex 5)	

Output 1.1	1	uality, policy-relevant data, evidence, and research on the pressing topics affecting			
Output ind	licator	Number of papers or reports completed/submitted to a journal			
		 Number of e 	evidence briefs published		
Baseline	Year	March 2024 • 0 papers or reports completed/submitted to a journal • 0 evidence briefs published			
Target	Year 1	By Dec 2024 • 2 papers or reports completed/submitted to a journal • 2 evidence briefs published			
Target	Year 2	By Dec 2025			
Target	Year 3	By Dec 2026	 4 papers or reports completed/submitted to a journal 5 evidence briefs published 		

Output 1.	2	Advance accessil	nce accessible, user-friendly evidence tools that summarise the lives and needs of AGYW			
Output in	dicato r	Number of Adolescent Atlas for Action (A3) dashboards added				
		Number of of	datasets added to the Adolescent Data Hub (ADH)			
Baseline	Year	March 2024	0 dashboards added to the A3			
			0 datasets added to the ADH			
Target	et Year 1 By Dec 20		1 dashboard added to the A3			
			10 datasets added to the ADH			
Target	get Year 2 By Dec 2025		1 dashboard added to the A3			
			20 datasets added to the ADH			
Target	Target Year 3 By Dec 2026		2 dashboards added to the A3			
			30 datasets added to the ADH			

Output 1.3	Facilitate knowledge translation to inform evidence-based policies, programs, and investments for AGYW					
Output indicator	 Number of events/webinars/briefings held with stakeholders Number of downloads or views of papers, reports, and evidence briefs Number of decision-makers who use PC data, research, or evidence in policy, programmatic, or investment decisions 					

Baseline	Year	March 2024	 0 event/webinar/briefing held with stakeholders 0 downloads or views of papers, reports, and evidence briefs 0 decision-makers who use PC data, research, or evidence in policy, programmatic, or investment decisions 	
Target	Year 1	By Dec 2024	5 events/webinars/briefings held with stakeholders 100 downloads or views of papers, reports, and evidence briefs 2 decision-makers who use PC data and evidence in policy, programmatic, or investment decisions	
Target	Year 2	By Dec 2025	 10 events/webinars/briefings held with stakeholders 200 downloads or views of papers, reports, and evidence briefs 4 decision-makers who use PC data and evidence in policy, programmatic, or investment decisions 	
Target	Year 3	By Dec 2026	 15 events/webinars/briefings held with stakeholders 300 downloads or views of papers, reports, and evidence briefs 5 decision-makers who use PC data and evidence in policy, programmatic, or investment decisions 	

Outcome 1 indicator: Number of global or national policies, strategic plans, and/or guidelines influenced by the evidence and tools generated by this development engagement

Dutput 1.1: Generate high quality, policy-relevant data, evidence, and research on the pressing topics affecting AGYW.

Building on the MFA's prior investment, the GIRL Center will continue producing high quality, policy relevant data, evidence, and research on the pressing topics affecting AGYW, such as education, SRHR, migration, mental health, climate, economic empowerment, and child marriage. PC will advance the field through

- (1) primary research to better understand what works, what does not work, and why;
- (2) secondary analyses and synthesis of data, such as literature and systematic reviews, to build global bodies of evidence;
- (3) modelling techniques to predict future trends;
- (4) cost effectiveness and benefit analyses to inform sound investments.

The focus is on producing publications in academic journals to reach technical and research audiences and a series of briefs summarising evidence to reach non-academic audiences including key global, national, and sub-national players and decision makers on adolescent health and development.

➤ Output 1.2: Advance accessible, user-friendly evidence tools that summarise the lives and needs of AGYW.

PC will continue to advance their suite of online user-friendly tools that promote use of data and evidence for policy makers, donors, program implementers, and researchers. Support from the MFA will specifically enable PC to scale up the Adolescent Atlas for Action (A3) and the Adolescent Data Hub (ADH).

- 1. The Adolescent Atlas for Action (A3), co-funded by the MFA, Children's Investment Fund, and the William and Flora Hewlett Foundation, is a suite of web-based dashboards that provides a multidimensional perspective on adolescent lives and experiences in LMICs. The A3 aims to arm adolescent-focused stakeholders with evidence and data to inform policies, programs, and investments. PC aims to add two new dashboards over the grant period.
- 2. In October 2022 the Adolescent Data Hub (ADH) 2.0 was launched with support from the MFA. As the world's largest catalogue of open-access data on adolescents, the ADH features more than 750 data sources from 138 countries. Since then, the site has been visited by 1,600 users. PC will add 10 new datasets to the ADH per year.

▶ Output 1.3: Facilitate knowledge translation to inform evidence-based policies, programs, and investments for AGYW.

PC will contribute to, host, or lead a series of events, webinars, and briefings with a range of stakeholders to share ideas and relevant and accurate evidence, foster the use of their tools, elevate conversations on adolescent girls, and promote integration within the ecosystem of adolescent girls' development. Tracking downloads or views of research products will help us understand the reach of their products. In addition, PC will employ qualitative discussions with key stakeholders to record concrete examples of how data, research, and evidence has enhanced decision-making and influenced policies, programs, practice, or investments.

Workstream 2: SRHR products

Outcome 2 Safe, affordable, effective microbicides and MPTs available to women where the need is greatest			ffective microbicides and MPTs available to women where the need is greatest
Outcome indicator 2		Number of microbicide and MPT products available in low- and middle-income countries	
Baseline	Year	March 2024 1 product (monthly dapivirine vaginal ring [DVR])	
Target	Year	December 2026	2 products (monthly DVR and three-month DVR)

Output 2.1	utput 2.1 Secure monthly DVR regulatory approvals in additional LMICs where there is an identified need product and expanding the monthly DVR use to additional population segments				
Output indicator			O new regulatory approvals (and/or import permits) obtained from National Medicines Regulatory Agencies (NMRAs) in identified LMICs. All approvals maintained.		
Baseline	Year	March 2024 8 NMRA approvals and 2 import licenses obtained (10 total)			
Target	Year 1	Dec 2024 3 additional approvals/import licenses secured (13 total)			
Target	Year 2	Dec 2025 3 additional approvals/import licenses secured (16 total)			
Target	Year 3	Dec 2026	3 additional approvals/import licenses secured (19 total approvals at end of the award)		

Output 2.2 Support for DVR access and market implementation to drive the uptake of DVR as an additional prevention option					
Output indicator		Provide technical expertise/assistance to country ministries of health (MOH) and other stakeholders (such as healthcare providers, implementation partners, and procurers) to support initiation and conduct of DVR implementation studies and related market introduction activities			
Baseline	Year	March 2024	14 implementation projects initiated		
Target	Year 1	Dec 2024 2 additional implementation projects initiated (16 total)			
Target	Year 2	Dec 2025 2 additional implementation projects initiated (18 total)			
Target	Year 3	Dec 2026	2 additional implementation projects initiated (20 total by the end of the award)		

Output 2.3 Building upon the monthly DVR, secure approvals, and support market introduction of a three-DVR as an alternative and lower cost option				
Output indicator			nical bioavailability clinical trial along with supportive product development studies required for ory and country NMRA approvals. Secure at least 1 regulatory approval	
Baseline	Year	March 2024 1 clinical trial ongoing		
Target	Year 1	Dec 2024 1 clinical study report completed		
Target	Year 2	Dec 2025 1 regulatory dossier under review		
Target	Year 3	Dec 2026	1 regulatory approval	

Output 2.4	Advance development of a multipurpose prevention technology (MPT) dapivirine-cont					
		towards regulatory approval and market access				
Output indicator		Implement a clinical trial program along with supportive product development studies required for stringent				
_		regulatory authority approval				
Baseline	Year	March 2024 1 clinical trial ongoing (Phase I)				
Target	Year 1	Dec 2024 1 clinical study report complete (Phase I)				
Target	Year 2	Dec 2025 2 clinical trials ongoing (HIV bioavailability and Phase II/III contraceptive efficacy)				
Target	Year 3	Dec 2026	1 clinical trial clinical study report complete (HIV bioavailability)			
			1 clinical trial ongoing (Phase II/III contraceptive efficacy)			

Outcome 2 indicator: Number of microbicide and MPT products available in low- and middle-income countries

➤ Output 2.1: Secure monthly DVR regulatory approvals in additional LMICs where there is an identified need for the product and expand the monthly DVR use to additional population segments.

The monthly DVR is the first discreet, long-acting, HIV-prevention product designed specifically for women. The regulatory strategy utilises the positive opinion issued by the European Medicines Agency (EMA) in combination with WHO prequalification to seek National Medical Regulatory Authority (NMRA) approvals in the countries where the product is needed the most.

MFA support will enable the PC to complete regulatory filings and associated activities to expand the number of countries where the monthly DVR has approval. This work includes new studies in response to regulatory feedback (if required), fulfilling regulatory agency specific requirements, engagement with regulators, and fulfilling requirements to be the DVR regulatory sponsor and market authorisation holder (MAH). Specifically, PC will:

- Maintain the monthly DVR dossier approvals from the EMA and all NMRAs thus far [Botswana, Kenya, Malawi, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe (including import licenses in Eswatini and Lesotho)].
- Support the review process for dossiers that have been submitted and are currently under review (Namibia, Tanzania, and Nigeria).
- Submit the dossier to additional NMRAs, beginning with Ethiopia, Mozambique, and Ghana. Additional countries will be based on need and interest.
- Maintain required licenses and registrations to be the MAH for the monthly DVR.
- Conduct all medical affairs and pharmacovigilance activities required to support the regulatory and market introduction process for the DVR.

➤ Output 2.2: Support for DVR access and market implementation to drive the uptake of DVR as an additional HIV prevention option.

Successful market introduction of a novel HIV prevention method like the monthly DVR requires extensive collaboration across sectors, including multi-lateral agencies, government, community-based, for-profit, and non-governmental organisations, to help ensure these products reach and are used by the populations that need them most.

In support of this, PC will utilise the DVR Market Access and Introduction Strategy (**Figure 2**), focused on action areas that cover community engagement, market access and implementation and policy and program support – the necessary components for product uptake.

Figure 2. DVR Market Access and Introduction Strategy

National Policy and Implementation Demand and Market **Community Engagement** Considerations Study Strategy & Support Programme Support & Partnerships · Additional research in National policies and Partnerships with civil Market analysis. Action Areas young women implementation plans society and advocates segmentation research · Donor and country-Healthcare provider & prototyping of Community initiated ring engagement in ring demand creation and training and implementation communication supervision materials rollout countries projects strategies /materials Conceptualizing early Product orders for ring introduction implementation Programmes (e.g., demo/pilot projects) projects

This work will be led by IPM South Africa, an affiliate of PC, and will continue to provide the necessary technical assistance and support to partners conducting implementation and demonstration projects to understand the real-world preferences and use of the monthly DVR as a part of a comprehensive HIV prevention package.

These activities will collectively ensure that this life-saving product can be brought through the early market-introduction phase and that real-world evidence inform broader roll-out in the countries where the women need these products the most.

➤ Output 2.3: Building upon the monthly DVR, secure approvals and support market introduction of a three-month DVR as an alternative and lower cost option.

The three-month DVR expands on the design of the approved monthly DVR, using the same flexible, silicone matrix polymer to slowly release dapivirine in the vagina with minimal systemic exposure. This product enables an extended-use option that many women may prefer and can also reduce cost, waste, and burden on health systems. Because the three-month DVR is a follow-on product to the approved, monthly DVR, already-completed regulatory activities for the monthly DVR will accelerate development of the three-month DVR. MFA funding will provide critical support for:

- Completion of a Phase I bioavailability trial to compare the pharmacokinetics of the three-month DVR to the one-month DVR.
- Completion of required chemistry manufacturing and controls (CMC) studies, including studies to define critical process parameters, such as active pharmaceutical ingredient dispersion.
- Development of a regulatory dossier for review by the EMA, WHO and African NMRAs.
 The three-month DVR will be submitted to the EMA for regulatory review as a "line-extension product," and PC anticipate that a positive Scientific Opinion from the EMA could be achieved as early as 2025. This will be used to seek WHO prequalification and to file necessary dossiers for approval. Per current timelines, African NMRA approvals are anticipated to begin in 2026.

Dutput 2.4: Advance development of a multipurpose prevention technology (MPT) dapivirine-contraceptive ring towards regulatory approval and market access.

Building off the monthly and three-month DVRs, this MPT contains the highly effective and widely used progestin levonorgestrel (LNG) for contraception. PC has prioritised MPT development as it has the potential to:

- (1) fill an unmet need for products that prevent both HIV and pregnancy;
- (2) increase overall uptake, adherence, and persistent use given the longer duration of effect versus the monthly DVR and ongoing motivation for protection from pregnancy versus both the one- and three-month DVRs;
- (3) expand the population of individuals using such a product, given it offers dual prevention, and may also reduce stigma associated with product that solely targets HIV prevention.

PC is currently evaluating two candidate dapivirine (DPV)-LNG rings to assess safety and pharmacokinetics over a 90-day exposure and to assess bleeding patterns, contributing the necessary data to select which ring formulation to advance. Exploratory objectives will look at ovarian function and the impact of body-mass index on LNG pharmacokinetics. Results are expected in early 2024. MFA funding would support PCs efforts to:

- Complete data analysis and the clinical study report of the aforementioned clinical trial.
- Engage with regulators (EMA and FDA) to confirm clinical and non-clinical requirements for review and approval of the DPV-LNG ring as a line-extension product of the monthly DVR.
- Prepare, implement, and complete an HIV efficacy bioavailability trial to bridge the efficacy of the monthly DVR to the DPV-LNG vaginal ring.
- Prepare and implement a DPV-LNG ring contraceptive efficacy trial.
- Implement and complete phase-appropriate CMC and characterisation studies required for regulatory review.

ANNEX 4: RISK MANAGEMENT

Contextual risks

Risk Factor	Likelihood	Impact	Risk response	Residual risk	Background to assessment
1.1 Unstable political and funding and operating climate with reduced attention and funding available for adolescent and SRHR topics.	High	Low	One of the Council's Strategic Objectives is to catalyse the use of data and evidence-based tools to inform smart policies and sound investments — this includes investing in adolescent girls and research and development of biomedical SRHR products. The Council's Corporate Finance & Administration division implements solutions in countries where currency devaluation impacts our ability to conduct our research.	The Population Council will continue to monitor and stay abreast of these trends. The Council's Resource Mobilisation strategy proactively addresses how the organisation can continue to diversity its funding base.	The new phase of this grant will be implemented against the backdrop of changing funding priorities due to the intersecting climate, humanitarian, and Ukraine crises. At the same time, governments around the globe are becoming more conservative on adolescent and SRHR issues. Additionally, many of the countries in which the Population Council operates are in the throes of financial crises and currency devaluation, affecting financial security for staff and institutions.
1.2. Project outputs are not used by decision makers and/or products are not integrated into global/national HIV prevention strategies	Low	High	The Population Council will leverage its longstanding relationships with governments, service delivery organisations, donors, and other relevant stakeholders. Early and ongoing conversations with end-users will secure buy-in and ensure evidence and the products we develop are responsive to their needs.	Subsequent, ongoing consultation will identify potential uptake barriers so that necessary adjustments can be met. Outputs will be produced in a range of engaging and accessible formats with change-focused content.	The project's ability to achieve real impact is contingent on political commitment and strong relationships with key stakeholders, including procurement agencies and country and local level influencers, to ensure the product can get into the hands of the end-users. A change in government, for example, can result in a more or less supportive political environment. The project results will be communicated in a range of formats and in person where the findings and their interpretation can be brought to bear on policy questions. It should also be recognised that some policy-level change may take place after the completion of this 3-year development engagement, given the time requirements often needed to yield this level of change, and the cyclical nature of some policies and strategic plans.

Programmatic risks

Risk Factor	Likelihood	Impact	Risk response	Residual risk	Background to assessment
2.1 Inappropriate or	Low	High	The Population Council has standard	Adhering to these procedures will avoid any	As a research institution, the Population Council
poor research design			procedures to ensure the both the	residual risk.	is adept at ensuring high quality research
or outputs			ethical conduct and high quality of		conforming to the highest ethical standards. The

			research. The Project Director will review research plans and project outputs to ensure they are scientifically sound.		Population Council has an Institutional Review Board (IRB), whose membership and structure adhere to the guidelines issued by the U.S. Department of Health and Human Services. As the proposed activities do not include primary data collection, they will not require full IRB review. The Population Council will submit plans to the IRB to obtain a determination that they are non-research and/or do not involve human subjects.
2.2. Poor quality outputs that do not meet the funder's expectations	Low	High	The project will be led by some of the Council's most senior staff who will directly contribute to the work and quality assure all outputs.	Adhering to standard quality assurance procedures will avoid any residual risk.	The Population Council has rigorous quality assurance processes in place to ensure high standards are met. The Population Council is known for its ability to attract, develop, and retain high calibre staff who directly contribute to and enhance the overall quality of the Population Council's work.
2.3 Challenges securing regulatory approval, WHO and country government level support	Low	High	DapiRing is in the WHO guidelines. The Council's affiliate organisation, IPM South Africa, engages with key stakeholders in the target countries and efforts have increased following the positive regulatory outcomes. We will follow this pathway for the DVR follow-on products	Ministries of Health or other similar incountry governmental agencies may not uptake the product even if we have worked to establish the appropriate local pathway for DVR and/or DVR follow-on product access.	DapiRing is being introduced through public health systems which require it to be added to country guidelines to allow for product procurement. There is a risk that there are challenges in these processes that can delay the introduction of DapiRing despite secured regulatory approvals.
2.4 Issues encountered during product development/ manufacturing	Low	Medium	The Product Development team in conjunction with the Quality Assurance Team closely manage all GMP and GLP activities to ensure any risks are identified and addressed in a timely and documented manner. The Clinical Affairs Team develops and implements formal Risk Management Plans as appropriate and per regulatory requirements	Even with the continued monitoring by the product development and quality assurance teams, product risks could occur. For example, having sole suppliers for the materials and manufacturing of the products runs the risk of supply chain disruptions.	Product related risks could be related to manufacturing or quality (e.g. potency, stability), nonclinical (e.g. toxicity) and/or clinical (e.g. physiological relevant interactions) and could affect the product's safety or efficacy in endusers.
2.5 Rumours about the microbicide products	Medium	Medium	IPM South Africa proactively plans for stakeholder and community engagement activities to mitigate rumours at their earliest stage	There is potential for rumours about the product in communities/countries where IPM South Africa has not recently engaged, or even in the communities where IPM South African is actively engaging.	There is a potential for harmful rumours in the research field, among stakeholders, and in target populations related to IPM products.
2.6 Challenges establishing pathways and strategies for	Low	Medium	IPM South Africa engages with global partners, and works with access and advocacy partnerships on national and local levels.	Ministries of Health or other similar in- country governmental agencies may not uptake the product even if we have worked to	Introducing a new HIV prevention product in sub-Saharan Africa is a complex endeavour which will require a range of in-country access activities including determining the optimal care

microbicide product		establish the appropriate local pathway for	delivery pathway, meeting the high level of
access		DVR and/or DVR follow-on product access.	education and awareness needed for health care
			providers required to drive ring prescription and
			appropriate use, supporting and increasing end-
			user acceptance of vaginal insertion and
			adherence to monthly product schedule. There is
			a potential risk that strong in-country presences
			and market activities will not be adequately
			established for DapiRing to enable the product to
			reach the women who will benefit from it. It is
			important that acceptable product pricing
			structures are maintained to support wide ring
			availability for various markets.

Institutional risks

Risk Factor	Likelihood	Impact	Risk response	Residual risk	Background to assessment
3.1 Bribery, fraud, or corruption involving funds causes reputational damage and/or lost funds	Low	High	Stringent financial management; Whistle-blower policy; training for staff; due diligence and monitoring for local partners; procurement policies; enterprise resource planning system; signing authority matrix; subcontracts require compliance with anti-bribery and corruption procedures; internal and external audits.	Residual risk is minimised given the Population Council's comprehensive systems and policies.	The Population Council has a well-developed, tightly-adhered-to financial management system for ensuring financial accountability for its work worldwide. The Population Council also has an established Enterprise Risk Management (ERM) structure and processes through which they routinely identify, assess, mitigate, monitor, and address potential organisational risks, including financial risks, and continually identify, assess, manage, and monitor the risks associated with conducting research and operational activities. The most recent (2022) independent financial audit by Grant Thornton had no findings or internal control issues.
3.2 The Population Council does not meet the conditions for a disbursement of funds	Low	Medium	Realistic work planning, regular project monitoring and communication with MFA, and robust financial management systems.	If necessary, the Population Council will draw on its unrestricted funding to mitigate changes in anticipated timing of payments so that project funding and delivery are not adversely affected.	The proposal details management structure, quality assurance, and dialogue plans, which will collectively ensure smooth implementation and continuity of the work.

ANNEX 5: BUDGET DETAILS

Table 1. Total Budget (DKK and USD) by Output

	ity through evidence and products	s that empower adolescent girls and
women	•	
	DKK	USD
Part 1: GIRL Center		
Output 1.1	6,065,102	895,013
Output 1.2	4,161,128	614,046
Output 1.3	4,773,769	704,452
Subtotal	15,000,000	2,213,512
Part 2: CBR		
Output 2.1	5,100,784	752,709
Output 2.2	5,620,499	829,402
Output 2.3	2,533,710	373,893
Output 2.4	1,745,008	257,506
Subtotal	15,000,000	2,213,509
	•	
GRAND TOTAL	30,000,000	4,427,021

Table 2. Annual Budget in DKK by Output

	2024	2025	2026	Total
Part 1: GIRL Center	·			·
Output 1.1	2,184,545	1,904,553	1,976,004	6,065,102
Output 1.2	1,340,096	1,452,799	1,368,233	4,161,128
Output 1.3	1,475,359	1,642,648	1,655,763	4,773,769
Subtotal	5,000,000	5,000,000	5,000,000	15,000,000
	·			·
Part 2: CBR				
Output 2.1	1,337,840	1,857,309	1,905,635	5,100,784
Output 2.2	1,473,018	2,045,620	2,101,861	5,620,499
Output 2.3	674,208	915,145	944,357	2,533,710
Output 2.4	454,958	633,368	656,683	1,745,008
Subtotal	3,940,023	5,451,442	5,608,535	15,000,000
		<u> </u>		<u> </u>
GRAND TOTAL	8,940,023	10,451,442	10,608,535	30,000,000

Table 3. Annual Budget in USD by Output

	2024	2025	2026	Total
Part 1: GIRL Cen	ter	<u>.</u>	<u>.</u>	<u>.</u>
Output 1.1	322,369	281,050	291,595	895,013
Output 1.2	197,754	214,386	201,906	614,046
Output 1.3	217,715	242,401	244,336	704,452
Subtotal	737,838	737,837	737,837	2,213,512
		·	·	
Part 2: CBR				
Output 2.1	197,421	274,078	281,209	752,709
Output 2.2	217,369	301,867	310,166	829,402

Output 2.3	99,491	135,045	139,356	373,893
Output 2.4	67,137	93,464	96,905	257,506
Subtotal	581,418	804,455	827,636	2,213,509
GRAND TOTAL	1,319,256	1,542,292	1,565,473	4,427,021

Overview of Total costs and co-funding

Tables 4 and 5 below separate direct costs per output from overhead costs, whereas summary tables 1-3 above show direct costs and indirect costs (overhead) as a single figure broken out by output. This leads to lower amounts per output presented below compared to tables above.

Table 4. Total Costs in DKK and Co-funding by Output

Cost in DKK (e	exchange rate USD,	'DKK = 6.7765	7)
Activity	Total cost	MFA funding	Other funding (amount and source)
Part 1: GIRL C	Center		
Output 1.1	16,072,257	5,668,320	1,882,381 – Wellspring Philanthropic Function (secured) 1,547,393 – Council Contribution (secured) 4,715,307 – Echidna Giving (secured) 2,258,857 – CIFF (anticipated)
Output 1.2	14,292,842	3,888,905	1,882,381 – Wellspring Philanthropic Fund (secured) 1,547,393 – Council Contribution (secured) 4,715,307 – Echidna Giving (secured) 2,258,857 – CIFF (anticipated)
Output 1.3	14,865,404	4,461,467	1,882,381 – Wellspring Philanthropic Fund (secured) 1,547,393 – Council Contribution (secured) 4,715,307 – Echidna Giving (secured) 2,258,857 – CIFF (anticipated)
Overhead	4,966,753	981,308	
Subtotal	50,197,256	15,000,000	
Part 2: CBR			
Output 2.1	11,778,844	4,767,088	6,165,507 - USAID LEADING (secured) 846,250 – Irish Aid (anticipated)
Output 2.2	27,984,363	5,252,803	2,653,766 – USAID LEADING (secured) 15,159,892 – EDCTP (anticipated) 1,840,702 – MSD (anticipated) 2,230,950 – Grand Challenges Canada (anticipated) 846,250 – Irish Aid (anticipated)
Output 2.3	30,656,201	2,367,953	22,769,101 – Germany (secured) 4,672,897 – Denmark (secured) 846,250 – Irish Aid (anticipated)
Output 2.4	48,064,098	1,630,848	15,536,128 – Germany (secured) 30,050,872 – USAID MATRIX (anticipated) 846,250 – Irish Aid (anticipated)

Overhead	40,448,046	981,308
Subtotal	158,931,552	15,000,000
GRAND TOTAL	209,425,234	30,000,000

Table 5. Total Costs in USD and Co-funding by Output

,	xchange rate USD		
Activity	Total cost	MFA funding	Other funding (amount and source)
Part 1: GIRL C	enter		077.700 W. II ' DI'I I ' E I
Output 1.1	2,371,742	836,461	277,788 – Wellspring Philanthropic Fund (secured) 228,345 – Council Contribution (secured) 695,825 – Echidna Giving (secured) 333,333 – CIFF (anticipated)
Output 1.2	2,109,156	573,875	277,788 – Wellspring Philanthropic Fund (secured) 228,345 – Council Contribution (secured) 695,825 – Echidna Giving (secured) 333,333 – CIFF (anticipated)
Output 1.3	2,193,647	658,367	277,788 – Wellspring Philanthropic Fund (secured) 228,345 – Council Contribution (secured) 695,825 – Echidna Giving (secured) 333,333 – CIFF (anticipated)
Overhead	732,930	144,809	
Subtotal	7,407,475	2,213,512	
Part 2: CBR Output 2.1	1,739,176	703,466	910,710 - USAID LEADING (secured)
o acpat 2.1	1,737,170	703,100	125,000 – Irish Aid (anticipated)
Output 2.2	4,132,832	775,142	391,989 – USAID LEADING (secured) 2,239,275 – EDCTP (anticipated) 271,891 – MSD (anticipated) 329,535 – Grand Challenges Canada (anticipated) 125,000 – Irish Aid (anticipated)
Output 2.3	4,527,903	349,432	3,363,235 – Germany (secured) 690,236 – Denmark (secured) 125,000 – Irish Aid (anticipated)
Output 2.4	7,099,338	240,660	2,294,849 – Germany (secured) 4,438,829 – USAID MATRIX (anticipated) 125,000 – Irish Aid (anticipated)
Overhead	5,974,460	144,809	, , ,
Subtotal	23,473,709	2,213,509	
GRAND TOTAL	30,881,184	4,427,021	

The budgeted program costs (i.e., costs budgeted under each of the outputs) include direct costs and quality assurance and oversight (QAO) costs, both of which are necessary to successfully implement the project. Direct costs include:

- all costs related to the actual time devoted by the Population Council staff for the implementation and the management of the activities;
- (ii) the proportionate share of related costs of fringe benefits and other directly apportioned costs for personnel whose specific inputs are required;
- (iii) other costs to implement project activities, such as travel, meetings, and supplies. QAO includes program management costs providing technical support, quality control, supervision, and management of the project technical and administrative staff necessary to achieve the results.

It should be noted that the Population Council's social and behavioural science research (including the work of the GIRL Center) and our biomedical research (i.e., CBR) are inherently different in nature and therefore employ different business models and costing strategies. Specifically, a large portion of CBR's work is laboratory-based, housed at Rockefeller University in New York. As a result, CBR's QAO costs also include office occupancy including rent and utilities per budgeted staff, costs for maintenance and repair for in house research laboratory equipment, annual certification inspections for certain laboratory equipment, and management of the Council's health and safety programs under the supervision of Rockefeller University's Laboratory Safety and Environmental health department.

AGYW/GIRL Center

General Staffing: This budget includes partial costs for the GIRL Center core team, including the GIRL Center Director – who will serve as the key point of contact with the MFA for this component of the grant, lead the overall direction of the work, and provide quality assurance; as well as the GIRL Center Manager, Coordinator, and Data Analyst. In addition, this grant will cover a new position – the Head of Policy, Partnerships, and Communications – which will enable the GIRL Center to elevate its communicating and convening work and deliver on our research uptake and impact goals. There is also time covered for the lead of the Council's Population, Environmental Risks, and the Climate Crisis (PERCC) initiative and two researchers who focus on adolescent and climate work.

• Output 1.1 – Generate high quality, policy-relevant data, evidence, and research on the pressing topics affecting AGYW

Total budget for Output 1.1 – 6,065,102 DKK

Funds will support staff time and related costs to conduct data analyses and evidence synthesis on critical issues related to adolescence – including climate, economic empowerment, and migration.

• Output 1.2 – Advance accessible, user-friendly evidence tools that summarise the lives and needs of AGYW

Total budget for Output 1.2 – 4,161,128 DKK

Funds will support staff time and related costs to maintain and expand the Adolescent Atlas for Action to include additional data sets, indicators, and interactive dashboards. Other costs include meetings and contractual fees for the web-based platform.

• Output 1.3 – Facilitate knowledge translation to inform evidence-based policies, programs, and investments for AGYW

Total budget for output 1.3 – 4,773,769 DKK

Funds will support staff time, meetings, and travel at country, regional and global levels to ensure that the evidence generated is shared with critical stakeholders, as well as the creation of written products that makes the learning accessible to non-research audiences.

SRHR/CBR

General Staffing: This budget includes the costs for the Chief Scientific Officer for the Population Council; the Vice President, Global Product Access and External Affairs; and the Chief Operating Officer at IPM South Africa, who will provide leadership of this effort in collaboration with the MFA. This will include providing technical guidance to the research, supervision of staff, and administrative support. In addition to leads for each output area, the Population Council has identified researchers to contribute to each. Research experts involved in each output will include Population Council and IPM South Africa researchers, as well as researchers from partner organisations with complementary expertise.

Output 2.1 – Secure monthly DVR regulatory approvals in additional LMICs where
there is an identified need for the product and expanding the monthly DVR use to
additional population segments

Total budget for output 2.1 – 5,100,784 DKK

Funds will support the staff time and costs related to activities required to complete regulatory filings and associated activities to expand the number of countries where the monthly DVR has approval. This work includes new studies in response to regulatory feedback (if required), fulfilling regulatory agency specific requirements, engagement with regulators, and fulfilling requirements to be the DVR regulatory sponsor and market authorisation holder (MAH).

• Output 2.2 – Support for DVR access and market implementation to drive the uptake of DVR as an additional HIV prevention option

Total budget for output 2.2 – 5,620,499 DKK

Funds will support the staff time and costs related to activities required to conduct DVR Market Access and Introduction Strategy activities, providing the necessary technical assistance and support to partners conducting implementation and demonstration projects to understand the real-world preferences and use of the monthly DVR as a part of a comprehensive HIV prevention package.

• Output 2.3 – Building upon the monthly DVR, secure approvals, and support market introduction of a three-month DVR as an alternative and lower cost option

Total budget for output 2.3 – 2,533,710 DKK

Funds will support the staff time and costs related to the activities necessary to advance the development of the three-month DVR through regulatory approval and into market introduction.

• Output 2.4 – Advance development of a multipurpose prevention technology (MPT) contraceptive-dapivirine ring towards regulatory approval and market access

Total budget for output 2.4 – 1,745,008 DKK

Funds will support the staff time and costs related to the activities necessary to advance the development of the three-month MPT contraceptive-dapivirine ring through late-stage clinical trials, which will result in the data necessary to advance the product through regulatory approval and into eventual market introduction.

Cross-output functions:

The budget includes costs related to the following functions that apply to all three outputs:

- 1. Strategic Communications, Creative Services, and Knowledge Management (KM): Includes time and international travel for the Population Council's Office of Strategic Communications staff to lead the project's Communication Plan (Annex 6); time for the Creative Services unit to ensure that products are visually appealing and communicated clearly and persuasively; and KM staff to monitor metrics related to the project outputs and ensure accessibility of research and outputs including open data.
- 2. Executive Engagement and Visibility: Includes time and international travel for the President and Chief of Staff. The President will provide strategic guidance; leverage resources from across the Population Council's research portfolio and international presence; and provide visibility to and represent the project to other partners and funders and in high-level fora. The Chief of Staff will serve as an overall institutional liaison to the MFA for both this engagement and other collaborations. The President and Chief of Staff will travel to Copenhagen to engage with the MFA and other stakeholders and will meet with MFA and Danish partners when they are in New York.
- 3. **Financial and Risk Management:** Includes preparation of financial reports and submission of technical and financial reports; procurement and subcontracts administration; and efforts to mitigate the institutional risks described in the Risk Management Matrix (Annex 4).

ANNEX 6: COMMUNICATION PLAN

Engagement title: Advancing gender equality through evidence and products that empower adolescent girls and women

Key Messages:

- Investing in AGYW and new SRH products advances global development goals, including the UN SDGs and Denmark's priorities for development cooperation to secure gender equality and girls and women's rights.
- Evidence-based approaches and meaningful participation of young people are essential to inform decision-making around the strategies for healthy transitions from adolescence to adulthood and to drive more strategic investments in AGYW.
- Women and adolescent girls need new and innovative SRH products that provide greater choice, convenience, and control; that enhance product uptake and effective use, and, ultimately, result in broad-based impact on SRHR outcomes.

Audiences: priority audiences are detailed in the Context Analysis (Annex 1) and include community stakeholders, civil society and advocacy groups, national governments, implementers, multilateral agencies and regional groupings, international and national NGOs, researchers, and donors.

Strategies:

- Engage key partners and end-users of research and evidence early and often to update on plans, invite feedback, and ensure evidence and outputs respond to needs.
- Ensure accessibility of research and outputs including open data through Dataverse and the Adolescent Data Hub, actionable insights through Adolescent Atlas for Action (A3) for decision makers, synthesis of evidence in easy-to-understand briefs, and open access scientific publications.
- Leverage platforms where key audiences engage, including convenings, conferences, online platforms, development publications, to showcase evidence and increase awareness and uptake of research, evidence, and recommendations.
- Develop intentional media and social media strategies to inform broader audiences about the challenges and opportunities related to investments in AGYW and SRH product development, and project findings.
- Utilise global milestones like the Commission on the Status of Women (CSW), the UN General Assembly (UNGA), United Nations Climate Change Summit (COP), the International Conference on Family Planning (ICFP), and Women Deliver to "launch" outputs, insights and perspectives and make the case for evidence-based investments in AGYW, deciphering the links between adolescents, population dynamics and climate change, and investing in new and innovative SRH products.
- Engage with key policymakers and different types of decision makers through national dialogue and strategic, one-on-one meetings.

Timeline:

Year 1 (March 2024 – December 2024)

• Package and promote research products from the MFA's prior investment in the GIRL Center.

- Hold regular trainings on new dashboards of the Adolescent Atlas for Action, and updated Adolescent Data Hub with key stakeholders to increase uptake.
- Develop specific strategies and plans for UNGA 2024, ICFP 2024, and COP29.
- Resurface (and as needed repackage) seminal pieces of research and raise the profile of 20+ years of work done by the Population Council about the case that investing in AGYW is a smart investment to achieve global health, social and economic progress.
- Segment key audiences and refine communications/dissemination channel(s) to reach them.
- Synthesise data from DVR market introduction and access activities, and follow-on DVR clinical trial results into slide decks/webinars and/or publications and/or presentations at scientific conferences and meetings.
- Quarterly project update presentations to the MFA.

Year 2 (January 2025 – December 2025)

- Dissemination side event based on first full year of work under this project during UNGA
 September 2025.
- Co-host a youth-related side event at COP30.
- Synthesise data from DVR market introduction and access activities, and follow-on DVR clinical trial results into slide decks/webinars and/or publications and/or presentations at scientific conferences and meetings.
- Quarterly project update presentations to the MFA.

Year 3 (January 2026 – December 2026)

- Lead pre-conference and/or side event at Women Deliver Conference (date TBC).
- Recommendations/roadmap shared with decision-makers for investment, possible side event at UNGA September 2026.
- Disseminate research findings by pursuing both widespread coverage of results and targeted dissemination to key stakeholders to contribute to the scientific evidence base, raise awareness of microbicide products and their potential, and cultivate continued support and demand for these products.
- Quarterly project update presentations to the MFA.
- Close out of the grant with presentation to the MFA, final publication, and webinar with key takeaways.

How:

• Evidence reviews, evidence briefs, reports, open-source peer-reviewed publications, webinars; Population Council newsletter; social media (Twitter/X, Facebook, LinkedIn); blogs; briefings; presentations at international conferences and meetings.

Process Action Plan (PAP) for Population Council

Action/product	Deadlines	Responsible/involved units	Comment/status
The project/programme	Ensure that the project	Responsible unit	
budget is inserted into the	budget is inserted into		
proposal for the Finance	the proposal for the		
Act	Finance Act – hearing		
	will be sent out by APD		
	(normally in		
	February/March)		
Identification	1	I	
Process Action Plan for	Min. 14 months prior	Responsible unit in	PAP to be updated at
project/programme	to the Minister's	consultation with potential	regular intervals
development up to the	approval	partners and Task Force, if	
registering of		established	
commitments			
Formulation, quality assura	I	T =	
Initiate development of	July-September	Responsible unit in dialogue	
Project/programme		with partner. Support from	
Document based on the		consultant, as needed.	
Identification Note			
Request for appraisal	September		Draft TOR for appraisal,
forwarded to ELQ			revised draft PAP and
			Draft Program Document
			and associated partner
Tandarinafanand			documentation
Tendering for and			One month mobilisation
contracting of appraisal			period
consultants, including			
mobilisation period			
Forward early draft of	29 September	Responsible unit and ELQ	An early draft should
project/programme		-	provide sufficient outline of
document to ELQ for			the intended
public consultation			project/programme without
			having all details fully
			fleshed out.
Meeting in Danida	24 October	ELQ and responsible unit	List of received responses
Programme Committee			from the consultation
Finalisation of the	October-November	Responsible unit	Summary conclusions from
project/programme			the Programme Committee
document			taken into account
Quality assurance:	November-December	Development specialist from	An independent view must
Appraisal		ELK or the responsible unit	be safeguarded during
			appraisal
Draft Appraisal Report,		Development specialist from	
including summary of		ELK or the responsible unit	
conclusions and			
recommendations			
Final appraisal report	December	Development specialist from	
integrating comments		ELK or the responsible unit	

from responsible unit and partner			
Final Project Document, annexes and appropriation cover note forwarded to ELQ	Min. 13 working days before meeting in Council for Development Policy	Responsible unit	
Presentation to the Council for Development Policy	First meeting in 2024	Responsible unit	
The minister approves the project		ELQ submits the proposed project/programme together with the minutes of meeting	After Council for Development Policy meeting
Document for Finance Committee (Aktstykke) and presentation to the Parliamentary Finance Committee, if applicable	After the Minister's approval		Only if direct legal basis for the commitment is not in place at Finance Act
Initial actions following the	Minister's approval	L	_
ELQ facilitates that grant proposals are published on Danida Transparency after the Minister's approval		ELQ	
Signing of Government- to-government agreement(s) and/or other legally binding agreements (commitments) with partner(s)	After the Minister's approval	Responsible unit	
Register commitment(s) in MFA's financial systems within the planned quarter	After agreement(s) are signed	Responsible unit	