### Ministry of Foreign Affairs – Department for Multilateral Cooperation and Policy (MUS)

# Meeting in the Council for Development Policy on 08 February 2024 Agenda Item No. 3

**1. Overall purpose:** For discussion and recommendation to the Minister

**2. Title:** Support to Population Council 2024-2026

**3. Amount:** DKK 30 million 2024-2026

**4. Presentation for Programme** 24.10.2023 **Committee:** 

**5. Previous Danish support** No presented to UPR:

# Support to the Population Council 2024-2026: 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 gender equality and women and girl's empowerment to increasing economic growth and creating more equal and democratic societies. 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

| File No.               | 2023-25154                                   |         |              |       |  |
|------------------------|--|---------|--------------|-------|--|
| Country                | Global                                       |         |              |       |  |
| Responsible Unit       | MUS  |         |              |       |  |
| 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        | Grants total 110,400,000 DKK from 1998-2023. |         |              |       |  |
| Finance Act code       | 06.36.03.3                                   | 11      |              |       |  |
| Head of unit           | Marie-Louise Koch Wegter                     |         |              |       |  |
| Desk officer           | Marie My Warborg Larsen                      |         |              |       |  |
| Reviewed by CFO        | YES: Ant                                     | onio U  | gaz-Simonse: | n     |  |
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**Relevant SDGs** [Maximum 1 – highlight with grey]

| 1 min<br>ttivitii<br>No<br>Poverty | 2 weeker<br>((()<br>No<br>Hunger | Good Health,<br>Wellbeing            | Quality Education             | Gender Equality                         | Clean Water, Sanitation              |
|------------------------------------|----------------------------------|--------------------------------------|-------------------------------|---|--------------------------------------|
| Affordable e Clean Energy          | Decent Jobs, Econ. Growth        | Industry, Innovation, Infrastructure | Reduced Inequalities          | Sustainable Cities, Communities         | Responsible Consumption & Production |
| 13 PRINCE INC.  Climate Action     | Life below Water                 | Life on Land                         | Peace & Justice, strong Inst. | 17 FEBRUSE SHIPS Partnerships for Goals |                                      |

#### Objective

Progress towards gender equality through the development and use of evidence and products that empower 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: Demonstrated understanding and use of evidence-based research by bilaterals, multilaterals, service delivery organizations and governments related to programmes and policies for AGYW that improve their overall health and well-being. | 15 DKK Million |
|---|----------------|
| Outcome 2: Safe, affordable, effective microbicides and MPTs available to women where the need is greatest  | 15 DKK Million |
| Total   | 30 DKK million |

### Project Document for single-partner project:

# Support to the Population Council 2024-2026: 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 'Support to the Population Council 2024-2026: Advancing Gender Equality through Evidence and Products that Empower Adolescent Girls and Women' as agreed between the parties: The Population Council (PC) and the Danish Ministry of Foreign Affairs 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, adolescent girls and young women (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 of school 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.

National legislation and policies that uphold and promote girls' and women's rights including their sexual reproductive health and rights (SRHR) are essential for development. 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 3rd and is headquartered in New York. The organisation's core area is biomedical, social science, and public health research to support 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 sexual reproductive health and rights (SRHR) and adolescent 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 – Population Council (popcouncil.org)</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 project supported by Denmark will support initiatives related to goal 1. Ensure sexual and reproductive health, rights, and choices (The Center for Biomedical Research) and goal 2. Empower adolescents and young people to reach their full potential (The GIRL Center).

#### 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 progress<sup>1</sup>. 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

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

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 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 Council's 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.

#### **Donors**

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), USAID, Irish Aid, Grand Challenges Canada, and the Government of Germany.

PC maintains collaborative relationships with current and former donors through bilateral communications and meetings, participation in conferences, and funder group-specific discussions e.g., the Product Development Partnership (PDP) Funders Group which Denmark is part of. PC also regularly shares evidence with donors to shape their current and future investments, with a focus on evidence-based programming. This engagement can range from one-on-one conversations, webinars, and learning sessions for donors to contracted work to conduct data-driven opportunity assessments. As a learning organisation, PC values donor engagement and incorporates donor feedback into its project plans. For example, the Evidence for Gender and Education Resource (EGER) has a Donor Advisory Group that meets quarterly to receive updates from PC and to give input into the project activities. The PC's International Committee for Contraception Research (ICCR) is an advisory board, including representatives from donor organisations, who provide guidance on PC's contraceptive and multi-purpose products under development.

#### Lessons learned

Denmark has supported the PC with several contributions in the period from 1998-2023 with a total of 110,400,000 DKK. From 1998-2009 and 2013-2015, Denmark provided annual, core support to PC, generally ranging from 4M to 9M DKK/year, enabling the necessary flexibility to explore new research ideas; sustain projects between funding cycles; and address issues often viewed by others as too complex or controversial. Such core funding has underpinned PC's longstanding work to develop and introduce contraceptive and HIV prevention products, and to pioneer a multisectoral approach to adolescent development — portfolios of work that continue to align with Denmark's priorities and have therefore received subsequent, direct support. Specifically, Denmark awarded PC 5M DKK from 2006-2010 to test innovative approaches to female condom programming; understand adolescent girls' HIV risk, safety, and protection strategies; and foster policy dialogue on HIV prevention programming for AGYW. Denmark renewed its support to PC in 2020, awarding 25M DKK (through June 2023), yielding a suite of research products and tools to inform evidence-based investments for AGYW, and further the world's understanding of the relationship between adolescents, population dynamics, and climate change. Denmark also awarded 5M DKK from 2022-2023 to support PC's efforts to ensure the DVR affordably reaches its intended end-users and advance follow-on products through the development pipeline.

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 and below are some examples.

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 (D&A) 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.

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 organisation 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 stakeholders.

The use of the research and resources provided by PC have not been utilised internally in the MFA 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.

The Adolescent Data Hub (ADH), an open-access data portal 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 conceptualise 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. PCs focus on integration of climate into their work with health is coherent with the Danish focus on integrating climate concerns into health systems as set out in the "How-to note on Climate adaptation, nature and environment." PC works globally with an emphasis on the African region, which aligns well with Danish priorities.

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. In addition, the Danish civil society organisations benefits from collaboration with PC: For Example, has AIDS-Fondet joined community advocates around the globe in calling for better access and more and better HIV prevention options, specifically for women, to increase choices beyond condoms and oral PrEP, which can be difficult for women in many contexts to access, negotiate and use. Here, the Population Council plays an important role in terms of its microbicide-related research, including implementation research projects on introducing the Dapivirine vaginal ring to the market in African countries and further development of the three-monthly combination contraceptive and PrEP ring. AIDS-Fondet and its partners works to amplify this effort and to advocate for equal access to new products. AIDS-Fondet's Ugandan partner organisation Lady Mermaid Empowerment Center (working on the rights and health of sex workers and their children) also participates in implementation studies for introduction of the Population Council's monthly Dapivirine vaginal ring in Uganda. In addition, AIDS-Fondet uses Population Council publications, insights and resources on sexual and reproductive health and rights and HIV prevention research and policy recommendations, including resources from the GIRL Center and from the Population, Environmental Risks, and the Climate Crisis (PERCC) initiative.

PC works closely with key multilateral organisations. For example, to establish and maintain a supportive environment for biomedical HIV prevention product introduction and rollout, PC and its affiliate, IPM South Africa, collaborate with The Global Fund, Unitaid, UNAIDS, and the World Health Organization (WHO). A strong example of this collaboration is the recent launch of the <u>UNAIDS Choice Manifesto</u>, which aims to reshape the advocacy agenda for access to HIV prevention tools and calls for continued political and financial support for HIV prevention choice. Similarly, PC works with The Global Fund and UNAIDS to support <u>DVR rollout in South Africa</u>. PC engages regularly with the WHO to maintain the DVR's prequalification, HIV prevention guidelines and recommendation, while working through with WHO collaborative registration procedure to seek accelerated in-country regulatory approval and subsequent integration into national HIV prevention policies.

PC staff are also called on for their expertise and to invited to participate in key technical working groups at UNAIDS. A recent example is the <u>UNAIDS Technical Expert Group on Social Enablers and HIV</u>, which helps set priorities for the global HIV prevention response. PC also advises the <u>WHO Human Reproduction Program</u> on a wide range of SRHR issues and adolescent health work – including strategy meetings and guideline development and review.

#### 3. Project Objective

The **objective** of this project is to advance progress towards gender equality through the development and use of evidence and products that empower adolescent girls and women. For nearly 50 years, PC has been at the vanguard of efforts to highlight the importance of investing in women. In a landmark, 1974 speech, PC's founder John D.

Rockefeller 3rd noted that "in all too many cases, women have been virtually neglected in development plans and programs". Yet today, systems of restrictive societal norms continue to challenge the world's effort towards achieving gender equality. Importantly, insufficient data inhibit global and national development policies and programs to address gender inequality, and the evidence on what works to achieve gender equality is evolving and complex. In line with PC's strategic objectives, 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. Specifically, this project focuses on advancing:

- Adolescent girls' empowerment: Demonstrated understanding and use of evidence-based research by bilateral, multilateral, service delivery organisations and governments related to programmes and policies for AGYW that improve their overall health and well-being; and
- 2. **SRHR:** Developing and introducing safe, affordable, effective microbicides and multi-purpose prevention technologies (MPTs) for adolescent girls and women where the need is greatest.

Adolescent girls' empowerment and SRHR are critical components of achieving gender equality — the equal distribution of power, resources, and opportunities among genders. As described in the context analysis, adolescent girls fare worse than boys on a range of outcomes, and women and girls are disproportionately affected by HIV. Ensuring sound investments in adolescent girls through evidence-informed programs and policies helps them grow into healthy adults, fostering a more gender-equitable world. And, improving SRHR — through the development and introduction of products that meet adolescent girls' and women's needs over the course of their reproductive lives — is a critical entry point to transform gender discriminatory structures, systems, norms, and stereotypes. The Theory of Change section provides further details on how the project's outputs will drive progress towards gender equality. Climate change is not a standalone pillar of PC's work, but rather a thread that weaves through a wide range of issues related to adolescents. Climate directly and indirectly affects adolescent SRHR, education, migration, child marriage and economic empowerment, exacerbating harmful gender norms and creating new challenges. Using novel satellite derived and remotely sensed datasets, as well as mixed methods research approaches, PC plans to integrate climate change into its activities, including it as a key potential factor shaping adolescents' transitions into adulthood. Proposed program or policy solutions that ensure that those transitions are safe, healthy, and productive, often developed in collaboration with direct beneficiaries and key stakeholders, will consider the disruption and insecurity caused by climate change to ensure solutions are effective and holistic.

The GIRL Center, via staff, internal, and external research collaborators, has a presence in 17 LMICs (Bangladesh, Benin, Burkina Faso, Egypt, Ethiopia, Ghana, Guatemala, India, Kenya, Malawi, Mexico, Nigeria, Pakistan, Senegal, South Africa, Zambia, and Zimbabwe). To work more directly in specific country contexts, the GIRL Center has established regional hubs, focused on East and Southern Africa (led out of Kenya), West Africa (led out of Senegal), South Asia (led out of India), and Latin America (led out of Guatemala). Its regional focal points engage in regional fora to ensure that evidence and data are part of the conversation and provide direct support to country-specific teams. Having different country and regional approaches allows PC to work in ways that are tailored to the challenges of the context. For example, some countries have high-quality data and sound policies, so PC's research uptake focuses on convening key stakeholders to better understand the gaps to evidence-based programming for adolescents. In other countries, there is a gap in the evidence base, so work is focused on conducting research itself. For example, the Sahel is one of the hardest regions to work in among those in which PC has a presence in due to the mix of humanitarian and development settings, and the relative lack of data and prior investment by development partners. Here, the GIRL Center is currently focused on a combination of research activities and providing technical assistance.

Currently, the DVR program is focused on Africa, where the need for HIV-prevention options for adolescents and women is the greatest, as determined by HIV incidence statistics from sources such as UNAIDS. For the monthly DVR, National Regulatory authority approval has been received in Botswana, Kenya, Malawi, Namibia, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe, with additional applications underway in additional countries; efforts are underway to conduct implementation studies/pilot programs and initiate product rollout. While the political and country context can vary greatly, PC's approach ensures government buy-in as a critical step and working in coordination with the country government along with local partners allows for an organised and collaborative product access and market introduction process that fits within that country's context.

#### 4. Theory of change and key assumptions

The **objective** of this engagement is to advance progress towards gender equality through the development and use of evidence and products that empower adolescent girls and women.

The theory of change seeks to achieve this objective through two discrete outcomes with associated indicators that align with the work streams this engagement encompasses, related to the GIRL Center's AGYW work and CBR's SRHR products, where PC can bring added value, and where positive change can contribute to achieving the project objective. Outputs 1.1-1.3 contribute to Outcome 1 and Outputs 2.1-2.4 contribute to Outcome 2. Together they will drive progress on the impact indicator: more policies, programs, practices, and products for adolescent girls and women based on the generation and use of research, evidence, and data.

- Outcome 1: The project contributes to the achievement of the SDG5 with an overall strategic goal of promoting gender equality through Demonstrated understanding and use of evidence-based research by bi-laterals, multilaterals, service delivery organizations and governments related to programmes and policies for AGYW that improve their overall health and well-being.
  - Output 1.1: Generate high quality, policy-relevant data, evidence, and research on the pressing topics affecting AGYW
  - Output 1.2: Advance accessible, user-friendly evidence tools that summarise the lives and needs of AGYW.
  - Output 1.3: Facilitate knowledge translation to inform evidence-based policies, programs, and investments for AGYW.

The audience for the activities of Outcome 1 are staff and decision-makers at bilateral, multilateral, service delivery organisations and LMIC governments as these are the individuals and institutions that will have the ability to use evidence to improve programs and policies for AGYW. PC will produce products that clearly communicate the research, and leverage relationships with stakeholders at the right political moments to foster change that improves the health and well-being of AGYW in LMICs.

Outcome 2: Safe, affordable, effective microbicides and MPTs available to women where the need is greatest

- Output 2.1: Maintain monthly DVR regulatory approvals received to date (10) from the EMA and African National Medical Regulatory Authorities (NMRAs) and expand the product label for use by additional population segments.
- Output 2.2: Support DVR access and market implementation to drive the uptake of DVR as an additional HIV prevention option.
- Output 2.3: Building upon the monthly DVR, secure regulatory approvals and begin market introduction of the three-month DVR as an alternative and lower cost HIV prevention option.
- Output 2.4: Advance the clinical development of a multipurpose prevention technology (MPT), the dapivirine-contraceptive ring.

**Note:** CBR works as a product development partnership (PDP), whereby its biomedical product development and introduction is made possible through coordinated financial and in-kind resources (inputs) from a variety of public, private and nongovernmental entities, including royalty-free licenses and exclusive rights to potent antiretroviral drugs (ARVs) to

develop microbicide products for HIV prevention. This leveraged co-funding model allows CBR to advance and make available a diverse portfolio of products. Denmark's 2024-2026 funding will directly contribute to the outcomes, outputs, and associated targets outlined in the Results Framework —in combination with other DVR-project funding (Irish Aid, USAID, BMBF Germany through KFW, and others TBA).

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.

Figure 1. Theory of Change

| Inputs   | $\rightarrow$        | Outputs  | Outcomes  | In  | pact  |
|--|----------------------|--|---|---|---|
| Population Council expertise from our presence in 14 countries offices with reach across 30 countries Ideas Research & technical expertise Funding Advice Ethical standards Partnerships Compounds & intellectual property for product development | 1.<br>2.<br>3.       | Generate high quality, policy-relevant data, evidence, and research on the pressing topics affecting AGYW Advance accessible, user-friendly evidence tools that summarise the lives and needs of AGYW Facilitate knowledge translation to inform evidence-based policies, programs, and investments for AGYW   | Promotion of gender equality through use of evidence-based research to better understand and implement programmes and policies related to AGYW that influence population dynamics, health and well-being, and the interface with climate change | Stronger evidence<br>base for decision<br>making     Increased<br>consideration of<br>evidence in decision<br>making     Greater consensus<br>on solutions     Fxpanded options                       | More effective policies, programs, practices     Decreased HIV infections and unplanned pregnancies     Improved SRH and women and girls' empowerment and self-care |
|  | 1.<br>2.<br>3.<br>4. | Secure monthly DVR regulatory approvals in additional LMICs Support for DVR access and market implementation to drive the uptake as an additional HIV prevention option Secure approvals, and support market introduction of a three-month DVR Advance development of a multipurpose prevention technology (MPT) daplivrine-contraceptive ring towards regulatory approval and market access | Safe, affordable, effective microbicides and MPTs available to women where the need is greatest   | Expanded options<br>for women-<br>controlled HIV<br>prevention     Increased uptake of<br>new ideas,<br>approaches and<br>products     Greater capacity to<br>use evidence     Smarter<br>investments |   |

- providers, and product end-users.
- Generate evidence on the safety and effectiveness of the DVR products
- Deliver accessible evidence through Peer-reviewed publications, Evidence synthesis briefs, Data dashboards, Policymaking decision tools, Viewpoints for traditional and social media Facilitate knowledge translation by convening stakeholders to engage with evidence, advising and strengthening capacity for evidence use, foster peer-to-peer learning, and review

The theory of change suggests that the situation for adolescent girls and women can be improved through support

- 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 tools, convenings and relationships are held and developed so that stakeholders both understand and value the data and evidence, as well are equipped with pathways for putting it into practice, and
- If microbicides for HIV prevention, and MPT products that provide protection against the dual threats of HIV-infection and unintended pregnancy 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 wellbeing of adolescent girls and women.

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. To date, CBR has made significant impact on the SRHR field as over 170 million women currently use a technology developed by CBR or a technological descendent.

Leveraging both in-house scientific capabilities and strong established partner collaborations that have helped PC achieve this, the vision is to continue 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 and promotes product access by developing partnerships and conducting awareness-raising, education, and market introduction activities.

#### **Key assumptions**

PC recognises that in order for change to occur, research and evidence, and their implications for policies and programs, must be effectively communicated and relevant to a range of key local to global stakeholders. Though beyond PC's control PC also leverages political moments and opportunities to facilitate change. 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.

The project is dependent on these stakeholders' interest in this area and willingness to create time to understand and implement from the body of work that PC is generating and synthesising. It also assumes stakeholders' interest in and prioritisation of adolescents' health and wellbeing will be maintained and not diverted by other national or global crises. It is also important to recognize that the process of fostering research use is not linear, and therefore does not always follow a predetermined timeline and workplan. The success of the project also relies upon the ability to capitalize on unanticipated but ripe opportunities to promote research uptake (e.g. a key issue is raised in the media), combined with trusted relationships with relevant decision makers. PC has a strong track record in this area. For example, following a media outcry of the prevalence of pregnant schoolgirls' sitting for exams, the government of Kenya turned to PC for evidence to inform its plans to address teenage pregnancy.

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 assumes continued extensive collaborations across sectors, including multilateral 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. For the DVR products a key part of supporting a successful, multi-country rollout is centering the voices of the users (women and AGYW), healthcare providers, and communities. The Pathway to DVR Access is built around four action areas:

## **DVR Access Program – Action Areas**



- Implementation Study Strategy & Support: PC is supporting implementation research in young women, as per EMA requirements, given the need for additional data. In addition to technical support, PC provides support for product orders.
- Demand and Market Considerations: PC conducts market analysis research to identify and understand
  different segments of potential ring users and then facilitates co-creation of prototypes for demand
  creation and communication strategies /materials by potential end-users for use by national stakeholders.

- National Policy and Programme Support: PC provides technical support for development of national
  policies and implementation plans, development and distribution of healthcare provider training and
  supervision materials, and support for conceptualizing early ring introduction programmes (e.g.,
  demonstration/pilot projects.
- Community Engagement and Partnerships: PC maintains key civil society partnerships for community awareness of the DVR and provides resources and maintains digital platforms for engagement.

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 project is furthermore dependent on a range of assumptions regarding women and girl's behaviour and opportunities. It is assumed that women and girls will have access to health facilities and prefer the new products produced by PC. A recent study showed that 2 out of 3 AGYW preferred the DVR compared to PrEP. Furthermore, it is assumed that women and girls will have the financial means to purchase the products developed by PC or that PC will be able to secure funding for implementation projects. With the current implementation of the 3-months DVR ring have secured funding and PC is implementing in collaboration with UNAIDS and the Global Fund.

In addition to reporting against the quantitative targets in the Results Framework, 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.

#### 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           | Denmark's Support to the Population Council 2024-2026:  |
|-------------------|---|
|                   | Advancing gender equality through evidence and products that empower adolescent girls and women             |
| Project Objective | Progress towards gender equality through the development and use of evidence and products that empower      |
|                   | adolescent girls and women.   |
| Impact Indicator  | More policies, programs, practices, and products for adolescent girls and women based on the generation and |
|                   | use of research, evidence, and data   |

| Outcome   | 1           | Demonstrated understanding and use of evidence-based research by bilaterals, multilaterals, service delivery |           |  |  |  |
|-----------|-------------|--|-----------|--|--|--|
|           |             | organizations and governments related to programmes and policies for AGYW that improve their or              |           |  |  |  |
|           |             | health and well-being.   |           |  |  |  |
| Outcome   | l indicator | Number of decision-makers who use PC data, research, or evidence in policy, programmatic, or investment      |           |  |  |  |
| decisions |             |  |           |  |  |  |
| Baseline  | Year        | March 2024 0 decision-makers who use PC data, research, or evidence in policy, programmatic, or              |           |  |  |  |
|           |             | investment decisions   |           |  |  |  |
| Target    | Year        | December 5 decision-makers who use PC data and evidence in policy, programmatic, or investme.                |           |  |  |  |
|           |             | 2026   | decisions |  |  |  |

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

| Output in | dicator | Number of papers or reports completed/submitted to a journal |  |
|-----------|---------|--|--|
|           |         | <ul> <li>Number of</li> </ul>                                | 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 access  | 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  |        | Facilitate know AGYW          | Facilitate knowledge translation to inform evidence-based policies, programs, and investments for AGYW |  |  |  |  |
|-------------|--------|-------------------------------|--|--|--|--|--|
| Output indi | cator  |                               | events/webinars/briefings held with stakeholders   |  |  |  |  |
|             |        | <ul> <li>Number of</li> </ul> | downloads or views of papers, reports, and evidence briefs   |  |  |  |  |
| Baseline    | Year   | March 2024                    | 0 event/webinar/briefing held with stakeholders  |  |  |  |  |
|             |        |                               | 0 downloads or views of papers, reports, and evidence briefs   |  |  |  |  |
| 77'         | 37 1   | D D 2024                      |  |  |  |  |  |
| Target      | Year 1 | By Dec 2024                   | • 5 events/webinars/briefings held with stakeholders   |  |  |  |  |
|             |        |                               | 100 downloads or views of papers, reports, and evidence briefs   |  |  |  |  |
| Target      | Year 2 | By Dec 2025                   | 10 events/webinars/briefings held with stakeholders  |  |  |  |  |
|             |        |                               | 200 downloads or views of papers, reports, and evidence briefs   |  |  |  |  |
| Target      | Year 3 | By Dec 2026                   | 15 events/webinars/briefings held with stakeholders  |  |  |  |  |
|             |        |                               | 300 downloads or views of papers, reports, and evidence briefs   |  |  |  |  |

| 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 approved and available in low- and middle-income countri |      |   | obicide and MPT products approved and available in low- and middle-income countries |  |  |
| Baseline  | Year | March 2024  | 1 product (monthly dapivirine vaginal ring [DVR])                                   |  |  |
| Target  | Year | December  | 2 products (monthly DVR and three-month DVR)  |  |  |
|   |      | 2026  |   |  |  |

| Output 2.1       |        | Maintain mont   | ntain monthly DVR regulatory approvals received to date (10) from the EMA and African National |  |  |  |  |
|------------------|--------|---|--|--|--|--|--|
|                  |        | Medical Regui   | Medical Regulatory Authorities (NMRAs) to ensure the product remains available; expand the     |  |  |  |  |
|                  |        | product label f   | or use by additional population segments   |  |  |  |  |
| Output indicator |        | All current and future approvals are maintained. All variations submitted to provide the evidence needed to |  |  |  |  |  |
|                  |        | expand the product indication to key populations (e.g., breastfeeding women, pregnant women and AGYW).      |  |  |  |  |  |
| Baseline         | Year   | March 2024  | NMRA approvals and import licenses received to date maintained (10 total)                      |  |  |  |  |
| Target           | Year 1 | Dec 2024  | 2 clinical and 2 Chemical, Manufacturing, and Control (CMC) variations submitted to EMA        |  |  |  |  |
| Target           | Year 2 | Dec 2025  | 2 clinical and 2 CMC variations submitted to WHO, and each African NMRA where                  |  |  |  |  |
|                  |        | approval has been received (10 total submissions)   |  |  |  |  |  |
| Target           | Year 3 | Dec 2026  | All monthly DVR product approvals/import licenses maintained                                   |  |  |  |  |

| Output 2.2 | Support DVR access and market implementation to drive the uptake of DVR as an additional HIV |
|------------|--|
|            | prevention option  |

| Output indicator Provide |        | Provide technica  | Provide technical 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  | nentation studies and related market introduction activities   |  |  |  |
| Baseline                 | Year   | March 2024  | Technical Support provided for the initiation of 0 additional/new implementation projects                    |  |  |  |
| Target                   | Year 1 | Dec 2024 Technical Support provided for the initiation of 2 additional/new implementation         |  |  |  |  |
| Target                   | Year 2 | Dec 2025 Technical Support provided for the initiation of 2 additional/new implementation project |  |  |  |  |
| Target                   | Year 3 | Dec 2026  | Technical Support provided for the initiation of 2 additional/new implementation projects                    |  |  |  |

| Output 2.3  | Building upon the monthly DVR, secure regulatory approvals and begin market introduction |   |  |  |  |  |  |
|-------------|--|---|--|--|--|--|--|
|             |  | three-month D   | VR as an alternative and lower cost HIV prevention option  |  |  |  |  |
| Output indi | cator  | Compilation of  | Compilation of clinical bioavailability data along with supportive product development study data into a |  |  |  |  |
|             |  | regulatory dossier to be submitted for stringent regulatory (EMA) and country NMRA approvals. Secure at |  |  |  |  |  |
|             |  | least 1 regulatory approval   |  |  |  |  |  |
| Baseline    | Year   | March 2024  | 1 clinical trial concluding (IPM 054 bioavailability study expected to end March 2024)                   |  |  |  |  |
| 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 the clinical development of a multipurpose prevention technology (MPT), the dapivirine-  |  |  |  |  |  |
|------------------|--------|--|--|--|--|--|--|
|                  |        | contraceptive v  | aginal ring  |  |  |  |  |
| Output indicator |        |  | Implementation of a clinical trial program, in parallel with the supportive product development studies required |  |  |  |  |
|                  |        | for stringent reg  | 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   | 2 clinical trials ongoing (HIV bioavailability and Phase II/III contraceptive efficacy)                          |  |  |  |  |

#### 6. Inputs/budget

The project budget is earmarked and divided evenly between the two outcomes and is split across the outputs contributing to the outcome. The reasoning for the even distribution is for Denmark to be able to maintain the support level from previous grants and continue the support to the two streams, which both remain a priority for Denmark.

| Project: Project: Advancing ge | ender equality thro | ugh evidence and produ | icts that empower ado | lescent girls and women |
|--------------------------------|---------------------|------------------------|-----------------------|-------------------------|
| 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              |
|                                |                     |                        |                       |                         |
| 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              |
|                                |                     |                        |                       |                         |
| GRAND TOTAL                    | 8,940,023           | 10,451,442             | 10,608,535            | 30,000,000              |

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:

| <b>Cost in DKK</b> (exchange rate USD/DKK = 6.77657) |  |
|--|--|
| Cost in Ditt (exchange rate Cob) Ditte = 0.77057)    |  |

| Activity        | Total cost  | MFA funding | Other funding (amount and source)  |  |  |  |
|-----------------|-------------|-------------|--|--|--|--|
| Outcome 1: GIRL | 4           |             |  |  |  |  |
| Center          |             |             |  |  |  |  |
| Output 1.1      | 16,072,257  | 5,668,320   | 1,882,381 – Wellspring Philanthropic Fund (secured)<br>1,547,393 – Council Contribution (secured)<br>4,715,307 – Echidna Giving (secured)<br>2,258,857 – CIFF (anticipated)  |  |  |  |
| Output 1.2      | 14,292,842  | 3,888,905   | 1,882,381 – Wellspring Philanthropic Fund (secured)<br>1,547,393 – Council Contribution (secured)<br>4,715,307 – Echidna Giving (secured)<br>2,258,857 – CIFF (anticipated)  |  |  |  |
| Output 1.3      | 14,865,404  | 4,461,467   | 1,882,381 – Wellspring Philanthropic Fund (secured)<br>1,547,393 – Council Contribution (secured)<br>4,715,307 – Echidna Giving (secured)<br>2,258,857 – CIFF (anticipated)  |  |  |  |
| Overhead        | 4,966,753   | 981,308     |  |  |  |  |
| Subtotal        | 50,197,256  | 15,000,000  |  |  |  |  |
|                 |             |             |  |  |  |  |
| Outcome 2: CBR  |             |             |  |  |  |  |
| Output 2.1      | 11,778,844  | 4,767,088   | 6,165,507 - USAID LEADING (secured)<br>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)<br>4,672,897 – Denmark (secured)<br>846,250 – Irish Aid (anticipated)   |  |  |  |
| Output 2.4      | 48,064,098  | 1,630,848   | 15,536,128 – Germany (secured)<br>30,050,872 – USAID MATRIX (anticipated)<br>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  |  |  |  |  |
|                 |             | <u> </u>    | the state of the s |  |  |  |

Danish funding represents approximately 30% of the total funding for Output 1. Within that, 40% is for Output 1.1, 28% is for Output 1.2 and 32% is for Output 1.3. Output 1.1 represents a slightly larger portion of the budget given its emphasis on evidence generation, which requires more resources and staff time. Outputs 1.2 and 1.3 represent research uptake activities and collectively represent the majority of the total output funding.

For Outcome 2, Danish funding will be utilized in combination with other DVR-project funding (Irish Aid, USAID, Grand Challenges Canada, BMBF Germany through KFW, and other TBA) to achieve the output indicators shown in the Results Framework. Given Denmark's contribution represents funding for the DVR, the funding is distributed across Outcome 2 budget to fill budgetary needs, with a focus on supporting the staff who work to develop and facilitate access to the DVR products.

Beyond the limits defined in the Financial Management Guideline, funds cannot be transferred between the budget lines without prior approval from the Danish Ministry of Foreign Affairs Expenditures beyond the total grant cannot be reimbursed to the Population Council.

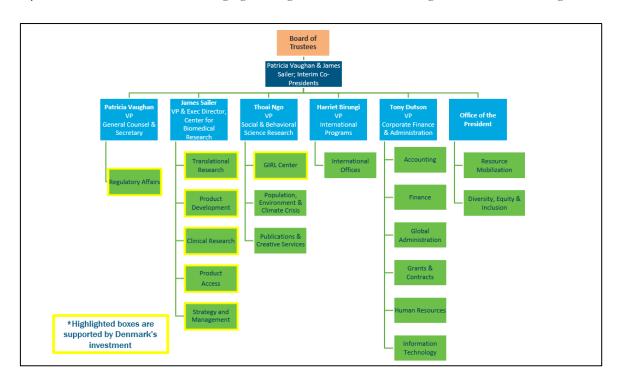
#### 7. Institutional and Management Arrangement

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

- 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. Dr. Brid Devlin, Chief Scientific Officer for CBR and Mr. Leonard Solai, 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.

Dr. Austrian and Ms. Ecker will be responsible for day-to-day project management, and will oversee annual work planning and budgeting, deliver progress reports as agreed with the MFA, and engage in regular dialogue with MFA to update on implementation and discuss any challenges. Their respective innovation hubs (i.e., Girl Center and CBR) are fully integrated into PC's organisational structure as integral parts of its Social and Behavioural Science Research (SBSR) and Biomedical Research divisions (see organigram, below). Overall management responsibility for each innovation hub falls under the respective PC Vice President, i.e., Dr. Thoai Ngo, VP for SBSR, and Mr. James Sailer, VP for CBR, who ensure institutional oversight and support for the project including visibility within and outside of PC, leveraging existing resources, and accessing institutional knowledge.



PC's Corporate Finance & Administration division is responsible for overall financial management of the project as detailed in Section 8. Financial Management, Planning, and Reporting, below.

#### Monitoring

PC will submit annual narrative and financial reports to the MFA. The reports will cover the overall status of the project, lessons learnt during the year with regard to the Theory of Change, challenges, and impacts. The progress reporting will include an update on risks and assumptions. These reports will inform learning and dialogue and feed into required adjustments and adaptation. The financial reporting shall be on the same detailed level as the budget. Semi-annual meetings will be used to share progress; discuss learning, challenges, and potential adaptation; and identify new opportunities to engage with Danish actors. One of these meetings will be after the submission of the annual reports to discuss the findings and possible adjustment to the project.

The Danish Ministry of Foreign Affairs 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 they 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. This arrangement has been chosen to align with the audit requirements of previous projects and engagements with PC and IPM.

#### 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 6: Monitoring Plan

Annex 7: Plan for Communication of Results

**Annex 8: Process Action Plan** 

Annex 9: Signed table of appraisal recommendations and follow-up actions taken

#### Poverty and Inequality Analysis

The 21<sup>st</sup> 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:

- Globally one in five young women are married while children.
- Globally 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.
- Globally 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.
- Globally 16 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.

### Fragility, Conflict, and Resilience

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 report<sup>2</sup> 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

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

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

<sup>3</sup> 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.

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.

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

<sup>&</sup>lt;sup>4</sup> "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

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

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 out-migration and the HIV serostatus of married women in rural India.7

#### Inclusive Sustainable Growth, Climate Change, and Environment

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.8 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

<sup>6</sup> 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.

<sup>7</sup> 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

<sup>8</sup> 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

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.

#### Annex 2: Partner assessment

Denmark has supported the Population Council (PC) with several contributions in the period from 1998-2015 and again from 2020-2023. Through these partnerships, the PC has delivered solid results and demonstrated capacity to manage Danish funds. Since 2015, Danish development officials have continued to have dialogue with the PC due to the extensive expertise offered by the PC 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.

#### **About Population Council (PC)**

The PC 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 PC.

The PC 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 PC staff currently counts approximately 375 Full Time Equivalent (FTE) staff, of which eighty-four are at the New York headquarter, sixteen in Washington DC, fifty-two at CBR (Maryland and South Africa) and 223 in the international offices. Kenya and India are the biggest offices with app. 80 FTE each. 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 PC 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.

Former IPM Board members and IPM staff have been integrated into the PC Board following the acquisition in line with the needs of PC and perceived value addition to the organisation. The integration/consolidation process is ongoing and will be finalised in 2024.

Each headquarter division as well as country office is responsible for fundraising and is supported by a central function to ensure quality and congruence with the PC strategy and priorities. The secured projects are implemented by in-house staff with external support/consultants being hired on a needs-basis.

#### The Girl Innovation, Research, and Learning (GIRL) Center

More than 25 years ago, the PC 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

Through its Center for Biomedical Research, the PC has developed and licensed some of the most widely used long-acting, reversible contraceptives in the world. The PC 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 PC 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 first approved 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 follow-on 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.

#### Financial management and administration

PC is well-consolidated with an equity of USD 109.7 million out of a balance sheet of USD 178.2 million as per the audited financial statements for 2022. The grants and contributions amounted to USD 45.8 million in 2022 against USD 42.5 million in 2021, whereas royalties were USD 4.8 million in 2022 and USD 5.6 million in 2021. The return on investments showed a negative of USD 10.8 million in 2022 whereas it was a solid plus of USD 14.9 million the year before. The 2022 solvency of 61% (equity over balance sheet) is very respectable and an equity above grants, donations, and royalties of more than 200% is rarely seen. The appraisal team found that PC is financially very sound.

PC has a centralised Corporate Finance and Administration division headed by a Vice President. The division covers all national and international financial matters, including accounting, finance, administration, grants and contracts and human resources. The financial matters are managed in a newly invested software based on Oracle software. It provides full international coverage and integration with other electronic platforms and continue making it possible to report on each individual funder and in accordance the proposed outputs and outcomes. The authority to financially commit PC is described in a Signing Authority and Delegation policy, which includes thresholds. The Global Procurement Policies & Procedures were latest updated in July 2021 and are of good standard and meet the MFA requirements.

The Global Conduct Policies from August 2022 includes, among others, policies for anti-trafficking, child protection, safe-guarding, conflicts of interest, discriminations, harassment, including sexual harassment, fraud and corruption, whistle-blowing arrangements. All staff must sign statements to that regard and are undergoing regular re-sensitisation. The policies and the adoption meet MFA requirements.

The annual external audit is conducted in accordance with auditing standards generally acceptable in the United States of America and not international standards as per MFA requirements. This implies that elements pertaining to compliance and performance are not duly considered. Historically, the use of Danish funds has been audited and included in the financial statements as a note (opening balance, funds received, funds used and closing balance) with the use on specific outcomes and outputs covered by a separate financial report.

The responsible MFA unit will carry out a full financial management capacity assessment in 2024.

#### 1. Summary of key partner features

| Partner                               | Core business  | Importance  | Influenc  | Contributio                                     | Capacity   | Exit   |
|---------------------------------------|--|---|---|---|--|--|
| name What is the name of the partner? | 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)? | e How much influence does the partner have over the programme (low, | n 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? |

|                       |  |  | medium,<br>high)?   |   |  |  |
|-----------------------|--|--|---|---|--|--|
| Population<br>Council | Research in population, health, and development, including in the fields of AGYW and biomedical research | Medium. The PC has a diversified donor base with govern-mental and private donors. This project enables the PC to further build on other active-tyes to maximize impact especially in the fields of AGYW wellbeing and HIV-prevention and biomedical research. | High. The PC will manage the delivery of project outputs. | The PC is<br>the only<br>partner thus<br>contributing<br>all results,<br>including<br>activities<br>previously<br>led by IPM. | Strong capacity with expertise in the particular research agendas addressed by the project, including with the acquisition of the IPM- related activities. | The PC has a diversified donor base and will be able to continue operations and activities building on the project results following end of the project. |

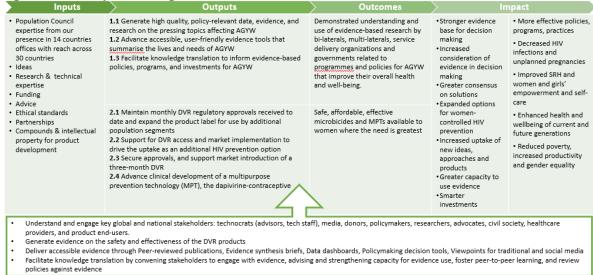
#### ANNEX 3: THEORY OF CHANGE AND RESULTS FRAMEWORK

The Population Council's (PC) unique combination of social science, public health, and biomedical research enables them 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.

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. To date, CBR has made significant impact on the SRHR field as over 170 million women currently use a technology developed by CBR or a technological descendent. Leveraging both in-house scientific capabilities and strong established partner collaborations that have helped them achieve this, the vision is to continue 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 and promotes product access by developing partnerships and conducting awareness-raising, education, and market introduction activities. For the DVR products a key part of supporting a successful, multi-country rollout is centring the voices of the users (women and AGYW), healthcare providers, and communities.

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           | Support to the Population Council 2024-2026:  |  |  |
|-------------------|---|--|--|
|                   | Advancing gender equality through evidence and products that empower adolescent girls and women             |  |  |
| Project Objective | Progress towards gender equality through the development and use of evidence and products that empower      |  |  |
|                   | adolescent girls and women.   |  |  |
| Impact Indicator  | More policies, programs, practices, and products for adolescent girls and women based on the generation and |  |  |
|                   | use of research, evidence, and data   |  |  |

#### Workstream 1: GIRL

| Outcome | e 1         | Demonstrated understanding and use of evidence-based research by bi-laterals, multi-laterals, service delivery |   |  |
|---------|-------------|--|---|--|
|         |             | organizations and governments related to programmes and policies for AGYW that improve their overall           |   |  |
|         |             | health and well-being.   |   |  |
| Outcome | 1 indicator | Number of deci   | sion-makers who use PC data, research, or evidence in policy, programmatic, or investment |  |
|         |             | decisions  |   |  |
| Baselin | Year        | March 2024   | 0 decision-makers who use PC data, research, or evidence in policy, programmatic, or      |  |
| e       |             | investment decisions   |   |  |
| Target  | Year        | December   | 5 decision-makers who use PC data and evidence in policy, programmatic, or investment     |  |
|         |             | 2026   | decisions   |  |

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

| Output 1         | .2     | Advance accessible, user-friendly evidence tools that summarise the lives and needs of AGYW |   |  |
|------------------|--------|---|---|--|
| Output indicator |        | 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       | 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                                 |  |

| Baseline | Year   | March 2024  | 0 event/webinar/briefing held with stakeholders                |
|----------|--------|-------------|--|
|          |        |             | 0 downloads or views of papers, reports, and evidence briefs   |
| Target   | Year 1 | By Dec 2024 | 5 events/webinars/briefings held with stakeholders             |
|          |        |             | 100 downloads or views of papers, reports, and evidence briefs |
| Target   | Year 2 | By Dec 2025 | 10 events/webinars/briefings held with stakeholders            |
|          |        |             | 200 downloads or views of papers, reports, and evidence briefs |
| Target   | Year 3 | By Dec 2026 | 15 events/webinars/briefings held with stakeholders            |
|          |        |             | 300 downloads or views of papers, reports, and evidence briefs |

Outcome 1 indicator: Number of decision-makers who use PC data, research, or evidence in policy, programmatic, or investment decisions

PC will track evidence use via surveying GIRL Center staff and collaborators, as well as reviewing the publications and websites of the stakeholders that have been engaged throughout each year. 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 and impacted the lives of AGYW.

# 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.

# Dutput 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 them understand the reach of their products.

### Workstream 2: SRHR products

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

| Output 2.1 Maintain montl |        | Maintain mont   | hly DVR regulatory approvals received to date (10) from the EMA and African National        |
|---------------------------|--------|---|---|
|                           | 7      |   | latory Authorities (NMRAs) to ensure the product remains available; expand the              |
|                           |        | product label f   | or use by additional population segments  |
| Output indi               | cator  | All current and   | future approvals are maintained. All variations submitted to provide the evidence needed to |
|                           |        | expand the prod   | luct indication to key populations (e.g., breastfeeding women, pregnant women and AGYW).    |
| Baseline                  | Year   | March 2024  | NMRA approvals and import licenses received to date maintained (10 total)                   |
| Target                    | Year 1 | Dec 2024 2 clinical and 2 CMC variations submitted to EMA             |   |
| Target                    | Year 2 | Dec 2025  | 2 clinical and 2 CMC variations submitted to WHO, and each African NMRA where               |
|                           |        |   | approval has been received (10 total submissions)   |
| Target                    | Year 3 | Dec 2026 All monthly DVR product approvals/import licenses maintained |   |

| Output 2.2  |        | Support DVR 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   | ders, implementation partners, and procurers) to support initiation and conduct of DVR        |  |
|             |        | implementation studies and related market introduction activities                            |   |  |
| Baseline    | Year   | March 2024   | Technical Support provided for the initiation of 0 additional/new implementation projects     |  |
| Target      | Year 1 | Dec 2024   | Technical Support provided for the initiation of 2 additional/new implementation projects     |  |
| Target      | Year 2 | Dec 2025   | Technical Support provided for the initiation of 2 additional/new implementation projects     |  |
| Target      | Year 3 | Dec 2026   | Technical Support provided for the initiation of 2 additional/new implementation projects     |  |

| Output 2.3  |        | Building upon the monthly DVR, secure regulatory approvals and begin market introduction of the        |   |  |  |
|-------------|--------|--|---|--|--|
|             |        | three-month D  | three-month DVR as an alternative and lower cost HIV prevention option                  |  |  |
| Output indi | cator  | Compilation of clinical bioavailability data along with supportive product development study data into |   |  |  |
|             |        | regulatory dossie  | er to be submitted for stringent regulatory (EMA) and country NMRA approvals. Secure at |  |  |
|             |        | least 1 regulatory   | approval  |  |  |
| Baseline    | Year   | March 2024   | 1 clinical trial concluding (IPM 054 bioavailability study expected to end March 2024)  |  |  |
| 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 the clinical development of a multipurpose prevention technology (MPT), the dapivirine-contraceptive ring |   |  |
|-------------|--------|---|---|--|
| Output indi | cator  | Implementation of a clinical trial program, in parallel with the supportive product development studies required  |   |  |
| for st      |        | for stringent reg   | ulatory 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  | 2 clinical trials ongoing (HIV bioavailability and Phase II/III contraceptive efficacy) |  |

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

Dutput 2.1: Maintain monthly DVR regulatory approvals received to date (10) from the EMA and African National Medical Regulatory Authorities (NMRAs) to ensure the product remains available; and expand the product label for use by 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:

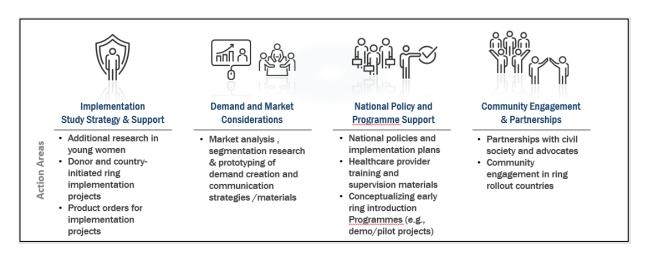
- Maintain the monthly DVR dossier approvals from the EMA and all NMRAs thus far [Botswana, Kenya, Malawi, Rwanda, South Africa, Uganda, Zambia, and Zimbabwe (including import licenses in Eswatini and Lesotho)].
- Support the review process for dossiers that have been submitted and are currently under review (Namibia, Tanzania, and Nigeria).
- Submit the dossier to additional NMRAs, beginning with Ethiopia, Mozambique, and Ghana.
- 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.
- Fulfil 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 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



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. The list below provides an overview of work that PC will do under each of the four action areas:

- For Implementation Study Strategy & Support PC are supporting implementation research in young women, as per EMA requirements, given the need for additional data. In addition to technical support, PC also provide support for product orders.
- For Demand and Market Considerations PC conduct market analysis research to identify and understand different segments of potential ring users and then facilitate co-creation of prototypes for demand creation and communication strategies /materials by potential end-users for use by national stakeholders.
- For National Policy and Programme Support PC provide technical support for development of national policies and implementation plans, development and distribution of healthcare provider training and supervision materials and support for conceptualizing early ring introduction Programmes (e.g., demo/pilot projects.
- For Community Engagement and Partnerships, PC maintain key civil society partnerships for community awareness of the DVR and provide resources and maintain digital platforms for engagement.

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 regulatory approvals and begin market introduction of the three-month DVR as an alternative and lower cost HIV prevention 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 threemonth 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.

# ➤ Output 2.4: Advance the clinical development of a MPT, the dapivirine-contraceptive vaginal ring.

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

| Contextual risl  | <u>ks</u>  |        |  |  |  |
|--|------------|--------|--|--|--|
| 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 | 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   | conduct our research.  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. |
| 1.3 Extreme weather caused by climate change damages local health infrastructure and disrupts health delivery services which can hinder PC in reaching | Medium     | Medium | The Population council uses their research on climate changes impact on health to adapt their programmes and projects.   | PC generates ideas and conducts research on sustainable and equitable solutions to pursue justice in the face of climate and environmental change.   | Climate change and degradation of nature often affect women and girls disproportionally. Climate change and its derived consequences not only bring to the fore the existing inequalities between men and women, but also reinforce power structures   |

| overall result. |  |  | and practices that hinder     |
|-----------------|--|--|-------------------------------|
|                 |  |  | progress towards gender       |
|                 |  |  | equality in line with the     |
|                 |  |  | general role of climate       |
|                 |  |  | change as an amplifier of     |
|                 |  |  | structural inequalities.      |
|                 |  |  | Further, climate change and   |
|                 |  |  | natural disasters continue to |
|                 |  |  | negatively impact SRHR and    |
|                 |  |  | impacts women and girls       |
|                 |  |  | more severely.                |

# Programmatic risks

| Risk Factor   | Likelihood | Impact | Risk response  | Residual risk   | Background to  |
|---|------------|--------|--|---|--|
| 2.1 Inappropriate or poor research design or outputs  | Low        | High   | The Population Council has standard procedures to ensure the both the ethical conduct and high quality of research. The Project Director will review research plans and project outputs to ensure they are scientifically sound.   | Adhering to these procedures will avoid any residual risk.  | As a research institution, the Population Council is adept at ensuring high quality research conforming to the highest ethical standards. The 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<br>securing<br>regulatory<br>approval, WHO<br>and country<br>government level<br>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 in-country governmental agencies may not uptake the product even if we have worked to establish the appropriate local pathway for DVR and/or DVR followon 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  | Low        | Medium | The Product  | Even with the continued   | Product related risks  |

| encountered<br>during product<br>development/<br>manufacturing                     |        |        | 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 | 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. | 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 end-users.   |
|--|--------|--------|---|---|--|
| 2.5 Rumours<br>about the<br>microbicide<br>products                                | Medium | Medium | IPM South Africa<br>proactively plans for<br>stakeholder and<br>community<br>engagement activities<br>to mitigate rumours<br>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 microbicide product access | 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 establish the appropriate local pathway for DVR and/or DVR follow-on product access.                | 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 delivery pathway, meeting the high level of 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

| mstrutional risks |            |        |                          |                            |                            |
|-------------------|------------|--------|--------------------------|----------------------------|----------------------------|
| Risk Factor       | Likelihood | Impact | Risk response            | Residual risk              | Background to              |
|                   |            |        |                          |                            | assessment                 |
| 3.1 Bribery,      | Low        | High   | Stringent financial      | Residual risk is minimised | The Population Council has |
| fraud, or         |            |        | management; Whistle-     | given the Population       | a well-developed, tightly- |
| corruption        |            |        | blower policy; training  | Council's comprehensive    | adhered-to financial       |
| involving funds   |            |        | for staff; due diligence | systems and policies.      | management system for      |
| causes            |            |        | and monitoring for       |                            | ensuring financial         |

| reputational     |     |        | local partners;          |                            | accountability for its work    |
|------------------|-----|--------|--------------------------|----------------------------|--------------------------------|
| damage and/or    |     |        | procurement policies;    |                            | worldwide. The Population      |
| lost funds       |     |        | enterprise resource      |                            | Council also has an            |
|                  |     |        | planning system; signing |                            | established Enterprise Risk    |
|                  |     |        | authority matrix;        |                            | Management (ERM)               |
|                  |     |        | subcontracts require     |                            | structure and processes        |
|                  |     |        | compliance with anti-    |                            | through which they             |
|                  |     |        | bribery and corruption   |                            | routinely identify, assess,    |
|                  |     |        | procedures; internal and |                            | mitigate, monitor, and         |
|                  |     |        | external audits.         |                            | 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          | Low | Medium | Realistic work planning, | If necessary, the          | The proposal details           |
| Population       |     |        | regular project          | Population Council will    | management structure,          |
| Council does     |     |        | monitoring and           | draw on its unrestricted   | quality assurance, and         |
| not meet the     |     |        | communication with       | funding to mitigate        | dialogue plans, which will     |
| conditions for a |     |        | MFA, and robust          | changes in anticipated     | collectively ensure smooth     |
| disbursement of  |     |        | financial management     | timing of payments so      | implementation and             |
| funds            |     |        | systems.                 | that project funding and   | continuity of the work.        |
|                  |     |        |                          | delivery are not adversely |                                |
|                  |     |        |                          | affected.                  |                                |

# DENMARK'S SUPPORT TO THE POPULATION COUNCIL 2024-2026

ADVANCING GENDER EQUALITY THROUGH EVIDENCE AND PRODUCTS THAT EMPOWER ADOLESCENT GIRLS AND WOMEN

> GIRL Center Center for Biomedical Research (CBR)



The Performance Monitoring Plan (PMP) provided in the table below describes the outcomes, outputs and associated indicators and targets from the project's Results Framework. This PMP is designed to establish the means and timeline of verification for each proposed output, along with our assumptions for achievement of the defined outputs and outcomes.

In addition, the Council 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.

Our annual reports will provide a narrative update of the project's progress, report achievements against targets, and examples of research uptake.

|   | Indicators  | Targets  | Means of Verification  | Assumptions   |
|---|---|--|--|---|
| Project Objective:  | Impact Indicator:   | Not applicable at this   | On an annual basis we  | Achieving the   |
| Project Objective: Progress towards gender equality through the development and use of evidence and products that empower adolescent girls and women.   | Impact Indicator: More policies, programs, practices, and products for adolescent girls and women based on the generation and use of research, evidence, and data | level  | On an annual basis we will reach out to select stakeholders who have used products generated through this project and document two case stories of how girls and women have been impacted by the policies, programs, practices, and products informed by the project.  | Achieving the project objective is contingent upon the assumptions outlined below.  |
| Outcome 1: Demonstrated understanding and use of evidence- based research by bi-laterals, multi- laterals, service delivery organizations and governments related to programmes and policies for AGYW that improve their overall health and well-being. | Outcome Indicator: Number of decision- makers who use our data, research, or evidence in policy, programmatic, or investment decisions                            | Baseline:  0 decision-makers who use our data, research, or evidence in policy, programmatic, or investment decisions Target at project completion: 5 decision-makers who use our data and evidence in policy, programmatic, or investment decisions | On a monthly basis all GIRL Center staff and collaborators will receive a monitoring survey to complete. There will be a question asking if any of the decision-makers they have interacted with in the past month have used their data, research, or evidence and if so, to describe the nature of it and provide links to any relevant documentation. This will be aggregated and reported.  GIRL Center staff will, on a quarterly basis, review the published documents and website of the stakeholders we engage with to search for any use of GIRL Center linked data, research or evidence. | Funding is available for AGYW programs.  Decision makers acknowledge that improving the health and wellbeing of AGYW is critical to overall development progress.  Decision makers are interested in supported evidence-based approaches for AGYW.  There are politically expedient moments that can be taken advantage of to implement research use. |
| Output 1.1<br>Generate high<br>quality, policy-   | Number of papers or reports completed/submitted   | Baseline: 0 papers or reports completed/submitted to a   | On a monthly basis all GIRL Center staff and collaborators will  | Research completed in a timely fashion to enable the  |

|                    | Indicators           | Targets                   | Means of Verification    | Assumptions           |
|--------------------|----------------------|---------------------------|--------------------------|-----------------------|
| relevant data,     | to a journal         | journal                   | receive a monitoring     | writing and           |
| evidence, and      |                      | 0 evidence briefs         | survey to complete       | publication of        |
| research on the    | Number of evidence   | published                 | indicating papers,       | results.              |
| pressing topics    | briefs published     | Year 1:                   | reports and evidence     |                       |
| affecting AGYW     |                      | 2 papers or reports       | briefs that have been    |                       |
|                    |                      | completed/submitted to a  | published and/or         |                       |
|                    |                      | journal                   | submitted. Information   |                       |
|                    |                      | 2 evidence briefs         | will be aggregated and   |                       |
|                    |                      | published                 | then included in the     |                       |
|                    |                      | Year 2:                   | narrative reports        |                       |
|                    |                      | 3 papers or reports       | submitted to the MFA.    |                       |
|                    |                      | completed/submitted to a  |                          |                       |
|                    |                      | journal                   | Publications reported    |                       |
|                    |                      | 4 evidence briefs         | in survey will be        |                       |
|                    |                      | published                 | verified by GIRL Center  |                       |
|                    |                      | Year 3:                   | Manager.                 |                       |
|                    |                      | 4 papers or reports       |                          |                       |
|                    |                      | completed/submitted to a  |                          |                       |
|                    |                      | journal                   |                          |                       |
|                    |                      | 5 evidence briefs         |                          |                       |
|                    |                      | published                 |                          |                       |
| Output 1.2         | Number of            | Baseline:                 | Quarterly review of the  | New analyses are      |
| Advance            | Adolescent Atlas for | 0 dashboards added to     | # of dashboards on the   | completed that lend   |
| accessible, user-  | Action (A3)          | the A3                    | A3 website               | themselves to         |
| friendly evidence  | dashboards added     | 0 datasets added to the   |                          | interactive data      |
| tools that         |                      | ADH                       | Quarterly tracking of    | visualization         |
| summarise the      | Number of datasets   | Year 1:                   | the # of datasets in the | dashboards that       |
| lives and needs of | added to the         | 1 dashboard added to the  | ADH by a query in the    | would fit with the    |
| AGYW               | Adolescent Data Hub  | A3                        | site or all datasets,    | A3.                   |
|                    | (ADH)                | 10 datasets added to the  | confirmed in the         |                       |
|                    |                      | ADH                       | backend of the site by   | Datasets are made     |
|                    |                      | Year 2:                   | the GIRL Center          | publicly available by |
|                    |                      | 1 dashboard added to the  | Manager                  | non-GIRL Center       |
|                    |                      | A3                        |                          | researchers that can  |
|                    |                      | 20 datasets added to the  |                          | be linked to via the  |
|                    |                      | ADH                       |                          | ADH.                  |
|                    |                      | Year 3:                   |                          |                       |
|                    |                      | 2 dashboards added to     |                          |                       |
|                    |                      | the A3                    |                          |                       |
|                    |                      | 30 datasets added to the  |                          |                       |
|                    |                      | ADH                       |                          |                       |
| Output 1.3         | Number of events/    | Baseline:                 | On a monthly basis all   | Stakeholders are      |
| Facilitate         | webinars/ briefings  | 0 event/webinar/briefing  | GIRL Center staff and    | interested in         |
| knowledge          | held with            | held with stakeholders    | collaborators will       | improving the         |
| translation to     | stakeholders         | 0 downloads or views of   | receive a monitoring     | health and wellbeing  |
| inform evidence-   |                      | papers, reports, and      | survey to complete       | of AGYW and are       |
| based policies,    | Number of            | evidence briefs           | indicating event,        | motivated to attend   |
| programs, and      | downloads or views   | Year 1:                   | webinars and briefings   | events, webinars      |
| investments for    | of papers, reports,  | 5                         | held. Information will   | and briefings on the  |
| AGYW               | and evidence briefs  | events/webinars/briefings | be aggregated and        | topic and download    |

|                   | Indicators            | Targets                                    | Means of Verification               | Assumptions                           |
|-------------------|-----------------------|--|-------------------------------------|---------------------------------------|
|                   |                       | held with stakeholders                     | then included in the                | and read papers,                      |
|                   |                       | 100 downloads or views                     | narrative reports                   | reports and                           |
|                   |                       | of papers, reports, and                    | submitted to the MFA.               | evidence briefs.                      |
|                   |                       | evidence briefs                            |                                     |                                       |
|                   |                       | Year 2:                                    | On a quarterly basis                | Papers, reports and                   |
|                   |                       | 10   | the GIRL Center                     | evidence briefs are                   |
|                   |                       | events/webinars/briefings                  | Manager will send the               | published online.                     |
|                   |                       | held with stakeholders                     | PC communications                   |                                       |
|                   |                       | 200 downloads or views                     | team a list of papers,              |                                       |
|                   |                       | of papers, reports, and                    | reports and evidence                |                                       |
|                   |                       | evidence briefs                            | briefs associated with              |                                       |
|                   |                       | Year 3:                                    | the GIRL Center and                 |                                       |
|                   |                       | 15   | they will check in our              |                                       |
|                   |                       | events/webinars/briefings                  | knowledge                           |                                       |
|                   |                       | held with stakeholders                     | management platform                 |                                       |
|                   |                       | 300 downloads or views                     | the number that each                |                                       |
|                   |                       | of papers, reports, and                    | one has been                        |                                       |
|                   |                       | evidence briefs                            | downloaded. The                     |                                       |
|                   |                       |  | information will then               |                                       |
|                   |                       |  | be aggregated for                   |                                       |
|                   |                       |  | reports.                            |                                       |
| Outcome 2: Safe,  | Outcome Indicator:    | Baseline:                                  | • Product                           | • Product is used                     |
| affordable,       | Number of             | 1 product (monthly dapivirine vaginal ring | approval/registration documentation | correctly and consistently            |
| effective         | microbicide and MPT   | [DVR])                                     | Product procurement                 | Positive public/end-                  |
| microbicides and  | products approved     | Target at project                          | logs                                | user perception of the                |
| MPTs available to | and available in low- | completion:                                | Product procurement                 | product                               |
| women where the   | and middle-income     | 2 products (monthly DVR                    | and availability data               | •Healthcare provider                  |
| need is greatest  | countries             | and three-month DVR)                       | provided in annual                  | knowledge,                            |
|                   |                       |  | technical reports shared            | acceptance and                        |
|                   |                       |  | with the DVR donor                  | support for the                       |
|                   |                       |  | community (PDP Funders              | product                               |
|                   |                       |  | Group Annual Report)                | •Adequate health                      |
|                   |                       |  |                                     | systems/capacity to                   |
|                   |                       |  |                                     | integrate the product  •Political and |
|                   |                       |  |                                     | economic stability in-                |
|                   |                       |  |                                     | country                               |
|                   |                       |  |                                     | •Sufficient global                    |
|                   |                       |  |                                     | financing to subsidize                |
|                   |                       |  |                                     | the cost of the product               |

|   | Indicators  | Targets   | Means of Verification  | Assumptions   |
|---|---|---|--|---|
| Output 2.1  | All current and future  | Baseline:   | •Approval  | No major issues   |
| Maintain monthly DVR regulatory approvals received to date (10) from the EMA and African National Medical Regulatory Authorities (NMRAs) to ensure the product remains available. Expand the product's label for use by additional population segments. | approvals are maintained. All variations submitted to provide the evidence needed to expand the product indication to key populations (e.g., breastfeeding women, pregnant women and AGYW).   | NMRA approvals and import licenses received to date maintained (10 total)  Year 1: 2 clinical and 2 CMC variations submitted to EMA  Year 2: 2 clinical and 2 CMC variations submitted to WHO, and each African NMRA where approval has been received (10 total submissions).  Year 3: All monthly DVR product approvals/import licenses maintained   | documentation from the regulators (Year 1 and 2) • Press Release or other announcement of the expanded product label (Year 2) • Results published in annual technical reports shared with the DVR donor community (PDP Funders Group Annual Report)  | identified during regulatory reviews. •EMA approves the clinical and CMC variations to the approved dossier, resulting in expanded population and indications for the monthly DVR product label. •WHO updates their recommendation to include the expanded population. •NMRAs approve the variations to the dossier, resulting in expanded population and indications for the monthly DVR product label for that country. |
| Output 2.2 Support DVR access and market implementation to drive the uptake of DVR as an additional HIV prevention option   | 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: Technical Support provided for the initiation of 0 additional/new implementation projects Year 1: Technical Support provided for the initiation of 2 additional/new implementation projects Year 2: Technical Support provided for the initiation of 2 additional/new implementation projects Year 3: Technical Support provided for the initiation of 2 additional/new implementation projects Year 3: Technical Support provided for the initiation of 2 additional/new implementation projects | •Press Release or other announcement of the initiation of new implementation studies (CBR in partnership with IPM South Africa and implementing partners). •Results published in annual technical reports shared with the DVR donor community (PDP Funders Group Annual Report). •Results presented at annual meetings with the DVR donor community and/or at technical conferences. •Results published in peer reviewed journals. •Technical support products (education materials) published on prepwatch.org. | Technical support activities can be conducted on schedule and on budget; no major technical barriers encountered. Sufficient resources are secured to provide continuous technical support.   |
| Output 2.3 Building upon the monthly DVR, secure regulatory approvals and begin market introduction of the three-month DVR  | Compilation of clinical bioavailability data along with supportive product development study data into a regulatory dossier to be submitted for   | Baseline: 1 clinical trial concluding (IPM 054 bioavailability study expected to end March 2024) Year 1: 1 clinical study report completed.   | •Results published in annual technical reports shared with the DVR donor community (PDP Funders Group Annual Report). •Results presented at annual meetings with the DVR donor community   | <ul> <li>Three-month DVR dossier submitted to EU-M4all as a monthly DVR line-extension product.</li> <li>Clinical and regulatory activities can be conducted on</li> </ul>  |

|  | Indicators   | Targets  | Means of Verification   | Assumptions  |
|--|--|--|---|--|
| as an alternative<br>and lower cost HIV<br>prevention option   | stringent regulatory<br>(EMA) and country<br>NMRA approvals.<br>Secure at least 1<br>regulatory approval.  | Year 2: 1 regulatory dossier under review Year 3: 1 regulatory approval  | and/or at technical conferences.  •Results published in peer reviewed journals.  •Product approval/registration documentation.  •Press Release or other announcement of regulatory approval of the three-month DVR.   | schedule and on budget; no major technical barriers encountered.  •No major issues identified during regulatory reviews •Data packages submitted are sufficient to support approval/positive scientific opinion by EMA, WHO prequalification.  •Sufficient resources are secured to complete submission of the regulatory dossier. |
| Output 2.4 Advance the clinical development of a multipurpose prevention technology (MPT), the dapivirine-contraceptive vaginal ring | Implementation of a clinical trial program, in parallel with the supportive product development studies required for stringent regulatory authority approval | Baseline: 1 clinical trial ongoing (Phase I) Year 1: 1 clinical study report completed Year 2: 2 clinical trials ongoing (HIV bioavailability and Phase II/III contraceptive efficacy) Year 3: 2 clinical trials ongoing (HIV bioavailability and Phase II/III contraceptive efficacy) | •Results published in annual technical reports shared with the DVR donor community (PDP Funders Group Annual Report). •Results presented at annual meetings with the DVR donor community and/or at technical conferences. •Results published in peer reviewed journals. •Press Release or other announcement of clinical trial results. | <ul> <li>Clinical activities         can be conducted on         schedule and on         budget; no major         technical barriers         encountered.</li> <li>Sufficient         resources are         secured to         implement the         clinical development         plan.</li> </ul>                                 |

#### ANNEX 7: COMMUNICATION PLAN

**Engagement title:** Support to the Population Council 2024-2026: 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 broadbased 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.

#### Responsible:

• Dr. Austrian and Ms. Ecker is responsible for the communication plan and the above mentioned activities in collaboration with their respectable teams in PC.

ANNEX 8: 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               |                         |                               |                               |
| Process Action Plan for      | Min. 14 months prior to | Responsible unit in           | PAP to be updated at regular  |
| project/programme            | the Minister's approval | consultation with potential   | intervals                     |
| development up to the        |                         | partners and Task Force, if   |                               |
| registering of commitments   |                         | established                   |                               |
| Formulation, quality assura  | ince and approval       |                               | 1                             |
| Initiate development of      | July-September          | Responsible unit in dialogue  |                               |
| Project/programme            | July supremise          | with partner. Support from    |                               |
| Document based on the        |                         | consultant, as needed.        |                               |
| Identification Note          |                         | consultant, as needed.        |                               |
| Request for appraisal        | September               |                               | Draft TOR for appraisal,      |
| forwarded to ELQ             | September               |                               | revised draft PAP and         |
| Tot warded to ELQ            |                         |                               | Draft Program Document        |
|                              |                         |                               | and associated partner        |
|                              |                         |                               | documentation                 |
| FI 1 : C 1                   |                         |                               |                               |
| 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 provide |
| project/programme            |                         |                               | sufficient outline of the     |
| document to ELQ for          |                         |                               | intended project/programme    |
| public consultation          |                         |                               | without having all details    |
|                              |                         |                               | fully fleshed out.            |
|                              |                         |                               |                               |
| Martina in Davida            | 24 October              | ELO Iit                       | T:                            |
| Meeting in Danida            | 24 October              | ELQ and responsible unit      | List of received responses    |
| Programme Committee          |                         |                               | from the consultation         |
|                              |                         |                               |                               |
| E. 1 C.1                     | 0 1 1 1                 | D 211 :                       |                               |
| Finalisation of the          | October-November        | Responsible unit              | Summary conclusions from      |
| project/programme            |                         |                               | the Programme Committee       |
| document                     | NT 1 1                  | D 1                           | taken into account            |
| Quality assurance: Appraisal | November-January        | Development specialist from   | An independent view must      |
|                              |                         | 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       | January                 | Development specialist from   |                               |
| integrating comments from    |                         | ELK or the responsible unit   |                               |
| responsible unit and partner |                         |                               |                               |
| Final Project Document,      | 22 January 2024         | Responsible unit              |                               |
| annexes and appropriation    |                         |                               |                               |
| cover note forwarded to      |                         |                               |                               |
| ELQ                          |                         |                               |                               |
| Presentation to the Council  | 8 February 2024         | Responsible unit              |                               |
| for Development Policy       | 5 - 552442, 2021        |                               |                               |
| The minister approves the    |                         | ELQ submits the proposed      | After Council for             |
| project approves the         |                         | project/programme together    | Development Policy meeting    |
| project                      | İ                       | 1 project/ programme together | Perciopinent Foney meeting    |

|   |                               | with the minutes of meeting |  |
|---|-------------------------------|-----------------------------|--|
| Document for Finance<br>Committee (Aktstykke) and<br>presentation to the<br>Parliamentary Finance<br>Committee, if applicable       | After the Minister's approval |                             | Only if direct legal basis for<br>the commitment is not in<br>place at Finance Act |
| Initial actions following the   | Minister's approval           | -L                          | I.   |
| ELQ facilitates that grant<br>proposals are published on<br>Danida Transparency after<br>the Minister's approval                    |                               | ELQ                         |  |
| Signing of Government-to-<br>government agreement(s)<br>and/or other legally binding<br>agreements (commitments)<br>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            |  |

#### 

| Exchange rate (DKK/other currency)                     | 1        |           |          |            |                |                |                |                |                |                | ]          |
|--|----------|-----------|----------|------------|----------------|----------------|----------------|----------------|----------------|----------------|------------|
|  | Unit     | Unit Cost | Quantity | Budget     | Year 1 (Q1-Q2) | Year 1 (Q3-Q4) | Year 2 (Q1-Q2) | Year 2 (Q3-Q4) | Year 3 (Q1-Q2) | Year 3 (Q3-Q4) | DKK        |
| Total Output 1-3                                       |          |           |          | 15.000.000 | 1.999.999      | 2.999.998      | 2.500.000      | 2.500.000      | 2.499.998      | 2.500.006      | 15.000.000 |
| Output 1.1   |          |           |          |            |                |                |                |                |                |                |            |
| Director, GIRL Center                                  | year     | 1.775.487 | 7 0,30   | 526.432    | 59.722         | 89.584         | 93.796         | 93.796         | 94.766         | 94.766         | 526.432    |
| Adolescent focused researchers                         | year     | 903.685   | 5 1,30   | 1.174.791  | 153.694        | 230.540        | 193.103        | 193.103        | 202.175        | 202.175        | 1.174.791  |
| Lead climate researcher                                | year     | 1.087.615 | 0,35     | 380.665    | 56.093         | 84.139         | 58.728         | 58.728         | 61.489         | 61.489         | 380.665    |
| Climate researher                                      | year     | 923.102   | 0,20     | 182.497    | 31.516         | 47.274         | 25.333         | 25.333         | 26.521         | 26.521         | 182.497    |
| Assoc. Director of Policy, Engagement and Partnerships | year     | 1.035.015 | 0,15     | 155.252    | 17.066         | 25.599         | 27.260         | 27.260         | 29.034         | 29.034         | 155.252    |
| GIRL Center Interns                                    | year     | 188.348   | 3 2,35   | 441.677    | 65.534         | 98.302         | 45.058         | 45.058         | 93.862         | 93.862         | 441.677    |
| Fringe Benefits  | year     | 2.419.637 | 7 0,33   | 738.825    | 98.423         | 147.635        | 120.699        | 120.699        | 125.685        | 125.685        | 738.825    |
| Office Costs   | year     | 391.077   | 7 1,33   | 521.280    | 71.880         | 107.819        | 84.248         | 84.248         | 86.542         | 86.542         | 521.280    |
| Office/Computer Equipment & Software                   | each     | 523.856   | 0,33     | 172.193    | 31.229         | 46.844         | 23.183         | 23.183         | 23.877         | 23.877         | 172.193    |
| Research Activities                                    | activity | 460.948   | 3 2,98   | 1.374.709  | 231.494        | 347.241        | 218.571        | 218.571        | 179.412        | 179.419        | 1.374.709  |
| Total direct cost output 1.1                           |          |           |          | 5.668.321  | 816.651        | 1.224.977      | 889.978        | 889.978        | 923.364        | 923.371        | 5.668.321  |
| Share indirect cost output 1.1                         |          |           |          | 396.782    | 57.166         | 85.748         | 62.298         | 62.298         | 64.636         | 64.636         | 396.782    |
| Total budget output 1.1                                |          |           |          | 6.065.103  | 873.817        | 1.310.725      | 952.277        | 952.277        | 988.000        | 988.008        | 6.065.103  |
| Output 1.2   |          |           |          |            |                |                |                |                |                |                |            |
| Manager, GIRL Center                                   | year     | 900.422   | 2 1,05   | 945.443    | 105.878        | 158.817        | 166.280        | 166.280        | 174.094        | 174.094        | 945.443    |
| Project Coordinator                                    | year     | 569.010   | 1,05     | 597.461    | 66.907         | 100.360        | 105.080        | 105.080        | 110.018        | 110.018        | 597.461    |
| GIRL Center Data Analyst                               | year     | 265.620   | 1,35     | 358.587    | 48.754         | 73.131         | 35.401         | 35.401         | 82.950         | 82.950         | 358.587    |
| Fringe Benefits  | year     | 1.901.491 | L 0,3:   | 598.500    | 69.025         | 103.538        | 98.821         | 98.821         | 114.147        | 114.147        | 598.500    |
| Office Costs   | year     | 377.082   | 2 1,86   | 701.557    | 84.378         | 126.567        | 111.031        | 111.031        | 134.275        | 134.275        | 701.557    |
| Dashboard development & Consultants                    | year     | 274.113   | 3 2,00   | 548.226    | 108.025        | 162.037        | 139.082        | 139.082        | -              | -              | 548.226    |
| Office/Computer Equipment                              | year     | 46.377    | 7 3,00   | 139.130    | 18.004         | 27.006         | 23.183         | 23.183         | 23.877         | 23.877         | 139.130    |
| Total direct cost output 1.2                           |          |           |          | 3.888.905  | 500.970        | 751.456        | 678.878        | 678.878        | 639.361        | 639.361        | 3.888.905  |
| Share indirect cost output 1.2                         |          |           |          | 272.223    | 35.068         | 52.602         | 47.521         | 47.521         | 44.755         | 44.755         | 272.223    |
| Total budget output 1.2                                |          |           |          | 4.161.128  | 536.038        | 804.057        | 726.400        | 726.400        | 684.117        | 684.117        | 4.161.128  |
| Output 1.3   |          |           |          |            |                |                |                |                |                |                |            |
| Director, GIRL Center                                  | month    | 1.777.700 | 0,30     | 533.310    | 59.722         | 89.584         | 93.796         | 93.796         | 98.206         | 98.206         | 533.310    |
| Manager, GIRL Center                                   | month    | 900.405   | 0,45     | 405.182    | 45.375         | 68.062         | 71.261         | 71.261         | 74.612         | 74.612         | 405.182    |
| Project Coordinator                                    | month    | 569.014   | 1 0,45   | 256.056    | 28.676         | 43.013         | 45.032         | 45.032         | 47.152         | 47.152         | 256.056    |
| Adolescent focused researchers                         | month    | 1.306.029 | 0,05     | 65.301     | 26.121         | 39.181         | -              | -              | -              | -              | 65.301     |
| Assoc. Director, Policy, Engagement and Partnerships   | month    | 1.034.991 | L 0,60   | 620.994    | 68.258         | 102.388        | 109.043        | 109.043        | 116.131        | 116.131        | 620.994    |
| Fringe Benefits  | month    | 1.880.844 | 1 0,27   | 511.241    | 63.231         | 94.846         | 86.040         | 86.040         | 90.542         | 90.542         | 511.241    |
| Office Costs   | month    | 376.665   | 0,93     | 351.733    | 43.233         | 64.850         | 60.012         | 60.012         | 61.813         | 61.813         | 351.733    |
| Convenings   | meeting  | 324.623   | 3 4,24   | 1.375.010  | 180.041        | 270.062        | 223.693        | 223.693        | 238.760        | 238.760        | 1.375.010  |
| Printing/Materials/Communications                      | year     | 18.549    |          |            | 7.202          | 10.802         | 9.273          | 9.273          | 9.548          | 9.548          | 55.647     |
| Travel   | lumpsum  | 35.874    | 1 8,00   | 286.991    | 29.677         | 44.516         | 69.443         | 69.443         | 36.957         | 36.957         | 286.991    |
| Total direct cost output 1.3                           |          |           |          | 4.461.467  | 551.536        | 827.304        | 767.592        | 767.592        | 773.721        | 773.721        | 4.461.467  |
| Share indirect cost output 1.3                         |          |           |          | 312.303    | 38.608         | 57.911         | 53.731         | 53.731         | 54.160         | 54.160         | 312.303    |
| Total budget output 1.3                                |          |           |          | 4,773,769  | 590.143        | 885.215        | 821.324        | 821.324        | 827.881        | 827.881        | 4.773.769  |

| Total Output 2.1-2.4   |   |                              | 15.000.000                             | 1.970.011        | 1.970.011        | 2.725.721        | 2.725.720        | 2.804.267        | 2.804.268        | 15.000.000          |
|--|---|------------------------------|--|------------------|------------------|------------------|------------------|------------------|------------------|---------------------|
| Output 2.1   |   |                              |  |                  |                  |                  |                  |                  |                  |                     |
| Chief Scientific Officer (CBR)   | /year 2.857.8   | 94 0,13                      | 82.777                                 | 10.788           | 10.788           | 15.061           | 15.061           | 15.540           | 15.540           | 82.777              |
| Senior Project Manager (CBR)   | /year 847.0   |                              | 61.330                                 | 7.993            | 7.993            | 11.157           | 11.157           | 11.515           | 11.515           | 61.330              |
| Associate Director, Grants Management (CBR)  | /year 885.0   |                              |  | 8.352            | 8.352            | 11.660           | 11.660           | 12.030           | 12.031           | 64.087              |
| Senior Director, Preclinical Sciences (CBR)  | /year 1.874.5   |                              | 407.207                                | 53.075           | 53.075           | 74.086           | 74.086           | 76.443           | 76.443           | 407.207             |
| Medical Affairs Support Specialist (SA)  | /year 203.0   |                              |  | 21.303           | 21.303           | 29.540           | 29.540           | 30.280           | 30.280           | 162.246             |
| Operations Support Associate (SA)  | /year 267.2   | ,                            | 213.550                                | 28.041           | 28.041           | 38.885           | 38.885           | 39.849           | 39.849           | 213.550             |
| Manager, Quality Mgmt and Compliance (SA)  | /year 410.7   |                              | 328.172                                | 43.091           | 43.091           | 59.754           | 59.754           | 61.241           | 61.241           | 328.172             |
| Chief Operating Officer (SA)   | /year 1.096.9   |                              | 657.290                                | 86.308           | 86.308           | 119.681          | 119.681          | 122.656          | 122.656          | 657.290             |
| VP, Pharmacovigilance & Medical Safety (SA)  | /year 778.2   |                              | 932.711                                | 122.473          | 122.473          | 169.831          | 169.830          | 174.052          | 174.052          | 932.711             |
| Specialist, Clinical Affairs (SA)  | /year 220.9   |                              | 264.797                                | 34.773           | 34.773           | 48.214           | 48.214           | 49.412           | 49.412           | 264.797             |
| RA Manager, Responsible Pharmacist (SA)  | /year 220.3   |                              | 571.764                                | 75.080           | 75.080           | 104.107          | 104.107          | 106.695          | 106.695          | 571.764             |
| Fringe Benefits - US Hire (CBR)  | /year 473.5   |                              | 205.424                                | 26.774           | 26.774           | 37.375           | 37.375           | 38.563           | 38.563           | 205.424             |
| Fringe Benefits - 03 Hire (CBK) Fringe Benefits - International Office Hire (SA)   | /year 2.411.1   | ,                            | 798.914                                | 104.905          | 104.905          | 145.469          | 145.469          | 149.084          | 149.084          | 798.914             |
|  | I''   |                              |  |                  |                  |                  |                  |                  |                  |                     |
| International Office Facilities (SA)  Total direct cost output 2.1   | /year 3   | 34                           | 16.817<br>4.767.087                    | 2.202<br>625.159 | 2.202<br>625.159 | 3.081<br>867.902 | 3.081<br>867.901 | 3.126<br>890.483 | 3.126<br>890.484 | 16.817<br>4.767.087 |
| Share indirect cost output 2.1   |   |                              | 333.696                                | 43.761           | 43.761           | 60.753           | 60.753           | 62.334           | 62.334           | 333.696             |
| ·  |   |                              |  |                  |                  |                  |                  |                  |                  |                     |
| Total budget output 2.1  |   |                              | 5.100.783                              | 668.920          | 668.920          | 928.655          | 928.654          | 952.817          | 952.818          | 5.100.783           |
| Output 2.2   |   |                              |  |                  |                  |                  |                  |                  |                  |                     |
| Chief Scientific Officer (CBR)   | /year 2.857.8   |                              |  | 10.948           | 10.948           | 15.279           | 15.279           | 15.781           | 15.781           | 84.016              |
| Senior Project Manager (CBR)   | /year 847.0   | 0,03                         | 124.533                                | 16.225           | 16.225           | 22.648           | 22.648           | 23.393           | 23.393           | 124.533             |
| Associate Director, Grants Management (CBR)  | /year 885.0   | 0,05                         | 65.056                                 | 8.475            | 8.475            | 11.831           | 11.831           | 12.222           | 12.222           | 65.056              |
| Senior Director, Strategy and Commercial Relations (CBR)   | /year 1.814.6   | 91 0,05                      | 133.389                                | 17.377           | 17.377           | 24.261           | 24.261           | 25.057           | 25.057           | 133.389             |
| Manager, Clinical Supply Chain (CBR)   | /year 799.6   | 36 0,01                      | 235.083                                | 30.627           | 30.627           | 42.754           | 42.754           | 44.161           | 44.161           | 235.083             |
| Senior Director, Preclinical Sciences (CBR)  | /year 1.874.5   | 90 0,03                      | 275.555                                | 35.899           | 35.899           | 50.117           | 50.117           | 51.762           | 51.762           | 275.555             |
| Medical Affairs Support Specialist (SA)  | /year 203.0   | 0,01                         | 65.874                                 | 8.646            | 8.646            | 11.991           | 11.991           | 12.301           | 12.301           | 65.874              |
| Manager, Quality Mgmt and Compliance (SA)  | /year 410.7   |                              | 33.306                                 | 4.371            | 4.371            | 6.064            | 6.064            | 6.218            | 6.218            | 33.306              |
| Chief Operating Officer (SA)   | /year 1.096.9   |                              | 889.615                                | 116.769          | 116.769          | 161.919          | 161.919          | 166.119          | 166.119          | 889.615             |
| Sr. Outreach Specialist (SA)   | /year 401.8   | 0,00                         | 488.801                                | 64.160           | 64.160           | 88.967           | 88.967           | 91.273           | 91.273           | 488.801             |
| Associate Director, Product Access & Medical Science Liaison (   | (//year 410.8   | 325 0,00                     | 499.767                                | 65.597           | 65.597           | 90.961           | 90.961           | 93.326           | 93.326           | 499.767             |
| VP, Product Access & External Affairs (SA)   | /year 967.7   |                              | 1.177.255                              | 154.525          | 154.525          | 214.270          | 214.270          | 219.832          | 219.832          | 1.177.255           |
| Specialist, Clinical Affairs (SA)  | /year 220.9   |                              | 44.805                                 | 5.881            | 5.881            | 8.155            | 8.155            | 8.366            | 8.366            | 44.805              |
| Fringe Benefits - US Hire (CBR)  | /year 917.6   |                              | 306.305                                | 39.906           | 39.906           | 55.708           | 55.708           | 57.539           | 57.539           | 306.305             |
| Fringe Benefits - International Office Hire (SA)   | /year 3.199.4   |                              |  | 107.171          | 107.171          | 148.610          | 148.610          | 152.465          | 152,465          | 816.493             |
| International Office Facilities (SA)   | I''   | 79 34                        |  | 1.750            | 1.750            | 2.364            | 2.364            | 2.361            | 2,361            | 12.950              |
| Total direct cost output 2.2   | 7,755   |                              | 5.252.803                              | 688.326          | 688.326          | 955.897          | 955.897          | 982.178          | 982.178          | 5.252.803           |
| Share indirect cost output 2.2   |   |                              | 367.696                                | 48.183           | 48.183           | 66.913           | 66.913           | 68.752           | 68.752           | 367.696             |
| Total budget output 2.2  |   |                              | 5.620.499                              | 736.509          | 736.509          | 1.022.810        | 1.022.810        | 1.050.930        | 1.050.930        | 5.620.499           |
|  |   |                              | 0.12.0.00                              |                  |                  |                  |                  |                  |                  |                     |
| Output 2.3   | 2.057   | 0.40                         | 00.050                                 | 10.015           | 10.016           | 45.000           | 45.000           | 45 704           | 45 704           | 22.050              |
| Chief Scientific Officer (CBR)   | /year 2.857.8   |                              |  | 10.916           | 10.916           | 15.232           | 15.232           | 15.781           | 15.781           | 83.859              |
| Senior Project Manager (CBR)   | /year 847.0   |                              | 124.300                                | 16.178           | 16.178           | 22.578           | 22.578           | 23.393           | 23.393           | 124.300             |
| Associate Director, Grants Management (CBR)  | /year 885.0   |                              | 64.934                                 | 8.450            | 8.450            | 11.795           | 11.795           | 12.222           | 12.222           | 64.934              |
| Senior Director, Strategy and Commercial Relations (CBR)   | /year 1.814.6   |                              | 53.265                                 | 6.933            | 6.933            | 9.676            | 9.676            | 10.024           | 10.024           | 53.265              |
| Manager, Clinical Supply Chain (CBR)   | /year 799.6   |                              | 117.327                                | 15.269           | 15.269           | 21.311           | 21.311           | 22.083           | 22.083           | 117.327             |
| Senior Director, Preclinical Sciences (CBR)  | /year 1.874.5   |                              | 275.039                                | 35.795           | 35.795           | 49.963           | 49.963           | 51.762           | 51.762           | 275.039             |
| Operations Support Associate (SA)  | /year 267.2   |                              | 54.092                                 | 7.092            | 7.092            | 9.835            | 9.835            | 10.120           | 10.120           | 54.092              |
| Manager, Quality Mgmt and Compliance (SA)  | /year 410.7   |                              | 166.239                                | 21.798           | 21.798           | 30.220           | 30.220           | 31.101           | 31.101           | 166.239             |
| Chief Operating Officer (SA)   | /year 1.096.9   |                              | 443.979                                | 58.218           | 58.218           | 80.711           | 80.711           | 83.060           | 83.060           | 443.979             |
| Sr. Outreach Specialist (SA)   | /year 401.8   |                              | 32.530                                 | 4.268            | 4.268            | 5.914            | 5.914            | 6.083            | 6.083            | 32.530              |
| Associate Director, Product Access & Medical Science Liaison (   | ( /year 410.8   |                              | 33.254                                 | 4.359            | 4.359            | 6.045            | 6.045            | 6.224            | 6.224            | 33.254              |
| VP, Product Access & External Affairs (SA)   | /year 967.7   |                              | 78.349                                 | 10.274           | 10.274           | 14.243           | 14.243           | 14.657           | 14.657           | 78.349              |
| ,  | I''   |                              | 157.501                                | 20.651           | 20.651           | 28.635           | 28.635           | 29.465           | 29.465           | 157.501             |
| VP, Pharmacovigilance & Medical Safety (SA)  | /year 778.2   |                              |  |                  |                  |                  |                  |                  |                  | FC 440              |
| VP, Pharmacovigilance & Medical Safety (SA)<br>Specialist, Clinical Affairs (SA)   | /year 778.2<br>/year 220.9                                    | 0,02                         | 56.449                                 | 11.729           | 11.729           | 8.130            | 8.130            | 8.366            | 8.366            |                     |
| VP, Pharmacovigilance & Medical Safety (SA)  | /year 778.2   | 0,02                         | 56.449                                 | 11.729<br>12.661 | 11.729<br>12.661 | 8.130<br>17.550  | 8.130<br>17.550  | 8.366<br>18.064  | 8.366<br>18.064  | 56.449<br>96.549    |
| VP, Pharmacovigilance & Medical Safety (SA)<br>Specialist, Clinical Affairs (SA)   | /year 778.2<br>/year 220.9                                    | 0,02<br>0,02<br>0,02         | 56.449                                 |                  |                  |                  |                  |                  |                  |                     |
| VP, Pharmacovigilance & Medical Safety (SA) Specialist, Clinical Affairs (SA) RA Manager, Responsible Pharmacist (SA)  | /year 778.2<br>/year 220.9<br>/year 477.0                     | 0,02<br>087 0,02<br>024 0,33 | 56.449<br>96.549                       | 12.661           | 12.661           | 17.550           | 17.550           | 18.064           | 18.064           | 96.549              |
| VP, Pharmacovigilance & Medical Safety (SA)<br>Specialist, Clinical Affairs (SA)<br>RA Manager, Responsible Pharmacist (SA)<br>Fringe Benefits - US Hire (CBR) | /year 778./ /year 220.9 /year 477.0 /year 718.7 /year 1.118.9 | 0,02<br>087 0,02<br>024 0,33 | 56.449<br>96.549<br>239.910<br>285.554 | 12.661<br>31.224 | 12.661<br>31.224 | 17.550<br>43.579 | 17.550<br>43.579 | 18.064<br>45.152 | 18.064<br>45.152 | 96.549<br>239.910   |

| Total direct cost output 2.3                             |           |           |         | 2.367.953 | 315.050 | 315.050 | 427.638 | 427.638   | 441.288 | 441.288 | 2.367.953 |
|--|-----------|-----------|---------|-----------|---------|---------|---------|-----------|---------|---------|-----------|
| Share indirect cost output 2.3                           | 165.757   | 22.054    | 22.054  | 29.935    | 29.935  | 30.890  | 30.890  | 165.757   |         |         |           |
| Total budget output 2.3                                  | 2.533.710 | 337.104   | 337.104 | 457.572   | 457.572 | 472.178 | 472.178 | 2.533.710 |         |         |           |
| Output 2.4   |           |           |         |           |         |         |         |           |         |         |           |
| Chief Scientific Officer (CBR)                           | /year     | 2.857.894 | 0,13    | 83.677    | 10.877  | 10.877  | 15.180  | 15.180    | 15.781  | 15.781  | 83.677    |
| Senior Project Manager (CBR)                             | /year     | 847.071   | 0,03    | 124.030   | 16.120  | 16.120  | 22.501  | 22.501    | 23.393  | 23.393  | 124.030   |
| Associate Director, Grants Management (CBR)              | /year     | 885.042   | 0,05    | 64.793    | 8.420   | 8.420   | 11.755  | 11.755    | 12.222  | 12.222  | 64.793    |
| Senior Director, Strategy and Commercial Relations (CBR) | /year     | 1.814.691 | 0,13    | 53.149    | 6.908   | 6.908   | 9.643   | 9.643     | 10.024  | 10.024  | 53.149    |
| Manager, Clinical Supply Chain (CBR)                     | /year     | 799.636   | 0,05    | 58.548    | 7.610   | 7.610   | 10.622  | 10.622    | 11.042  | 11.042  | 58.548    |
| Scientist II, Formulation Technology (CBR)               | /year     | 970.522   | 0,02    | 213.127   | 27.700  | 27.700  | 38.666  | 38.666    | 40.197  | 40.197  | 213.127   |
| Senior Director, Preclinical Sciences (CBR)              | /year     | 1.874.590 | 0,05    | 137.232   | 17.836  | 17.836  | 24.896  | 24.896    | 25.884  | 25.884  | 137.232   |
| Operations Support Associate (SA)                        | /year     | 267.291   | 0,10    | 10.797    | 1.416   | 1.416   | 1.959   | 1.959     | 2.024   | 2.024   | 10.797    |
| Manager, Quality Mgmt and Compliance (SA)                | /year     | 410.746   | 0,02    | 82.944    | 10.860  | 10.860  | 15.061  | 15.061    | 15.551  | 15.551  | 82.944    |
| Chief Operating Officer (SA)                             | /year     | 1.096.940 | 0,02    | 221.499   | 29.002  | 29.002  | 40.218  | 40.218    | 41.530  | 41.530  | 221.499   |
| VP, Pharmacovigilance & Medical Safety (SA)              | /year     | 778.284   | 0,02    | 157.157   | 20.577  | 20.577  | 28.537  | 28.537    | 29.465  | 29.465  | 157.157   |
| Specialist, Clinical Affairs (SA)                        | /year     | 220.957   | 0,02    | 44.623    | 5.843   | 5.843   | 8.102   | 8.102     | 8.366   | 8.366   | 44.623    |
| Fringe Benefits - US Hire (CBR)                          | /year     | 734.555   | 0,33    | 245.195   | 31.868  | 31.868  | 44.483  | 44.483    | 46.246  | 46.246  | 245.195   |