

# Technical Considerations for Supply Chain for Health and Research

4TH Annual Global Health Local Partner Meeting



# **Defining Localization in PEPFAR's Supply Chain:**

A Practical Guide to Decision Making and Planning for Sustainable and Resilient Supply Chains

2022 Local Partners Meeting (LPM4) Johannesburg, South Africa

Supply Chain for Health Division (SCH)
USAID Office of HIV/AIDS
Bureau for Global Health

# Agenda

- Defining localization in the context of supply chains
- Understanding supply chain actors
- Current state of localization and examples
- Guiding principles
- Suggestions for developing localization strategy

Defining Localization in the Context of Supply Chains



# What do public health supply chains look like?

	Models	Product selection	Forecasting	Price negotiation & contract	Purchasing	Ordering	Storage & distribution	Contract performance management	Example countries
1	CMS	Central government				Facility may order through 'pull' mechanism	CMS system	Typically NA	Malawi
2	Autonomous supply agencies	Central parastatal agency				Facility may order through 'pull' mechanism	Parastatal agency	Typically NA	Zambia (MSL) or Kenya (KEMSA)
3	Direct delivery system		Pharmaceutical procurement office (PPO) at the central government or global level			Facility or sub-national government orders from suppliers	Suppliers manage	Central or sub-national government	South Africa (Centralized Chronic Medication Dispensing and Distribution program and Facility Direct Delivery Program)
4	Pre-qualified vendor (s)	Central government	entral government—Pharmaceutical procurement office (PPO)			Facility or sub-national government orders from distributors	Distributors manage	Central	US VA/DoD and Tanzania
5	Facility purchasing	Central government determines through STGs and EML (HFs may not adhere)					Facility manages either self-storage or through arrangements with private suppliers/ distributors	Typically NA	Countries with OOP expenditures- based financing for medicine purchase (e.g., Nigeria, India)

Most PEPFAR supported public health supply chains are hybrids of the models presented here

Table Source:

Decentralized Purchasing of Essential Medicines and Its Impact on Availability, Prices, and Quality: A Review of Current Evidence, Lyudmila Nepomnyashchiy and Prashant Yadav

# Who are the main actors in public health supply chains?



Forecasting & Supply Planning



Buying



Sourcing & Manufacturing



QΑ OC



Global Transport



Global Stock Centers



Customs Clearance



National Storage Level



In-Country Transport



Sub-National Storage Level



Last Mile Delivery



Service Level Delivery

- Manufacturers
- Wholesalers
- **Partner Governments** 
  - Central
  - Sub-national
- **Parastatals**
- Donors
- Private sector
  - Warehouse operators
  - **Transport providers**
  - 4th party logistics
- Hospitals and health facilities (in the ordering capacity)

# What does localization mean in supply chain terms?

### How it is measured by S/GAC

 Direct contracts (bi-lateral awards with local companies, G2G, parastatals, etc.) that can be measured by funding amounts

### What it also includes, but isn't measured

- Contracting with local stakeholders, companies, and technology firms to provide supply chain services and goods reflective of PEPFAR and USAID global health standards and benchmarks.
  - Categories: procurement, logistics, and technical assistance (and others)

# — Localization Examples



# **Current State of Funding of Local Entities:** while GHSC-PSM funds multiple local entities as subcontractors, only direct awards with USAID count towards

# P21 Prime Contractor with Local Sub-Contracts



### 56 Local Subcontractors Through GHSC-PSM

In COP21, GHSC-PSM has subcontracts with locally owned and operated entities, but PEFAR does not count these awards towards the 70% goal

# COP21 G2G or Parastatal Awards



### **5 Countries with G2G or Parastatal Awards**

\$16,438,028 in PEPFAR funding (Ghana/DRC funding through other health element)

Parastatals and G2Gs have differing legal and contractual designations within the FAR and ADS

### **COP21 Local Bilateral Awards**



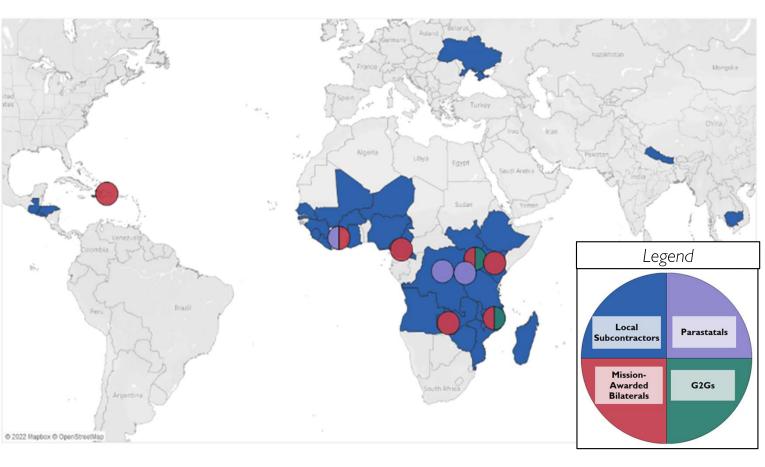
### **5 Countries with Direct Bilaterals**

\$44,237,722 in PEPFAR funding (excluding Cote d'Ivoire, and does not include MEDS in Kenya.

# Current State of Funding of Local Entities: engagement takes different forms

# across countries and all health elements

USAID Countries with G2G, Parastatal, and Bilateral Awards and GHSC-PSM Local Subcontractors in Supply Chain across the PEPFAR, PMI, PRH & MNCH Portfolios



- USAID and PEPFAR investment in local entities is realized through various mechanisms
- Direct awards include locally awarded bilaterals and G2Gs/Parastatals
- Graphic also depicts a series of local subcontracts through centrally managed awards for 3PL distribution, warehousing and other services

# Local mechanisms in Mozambique

Mechanism Name	Туре	Function	Current Status	COP20 Funding	COP21 Funding	Future Status
CMAM	G2G	Outsourcing management	Active	\$341,940	\$341,940	
CHEGAR	Private Sector	Commodity distribution & transportation	Active, Awarded June 2021	\$5,950,000	\$9,063,0 23	3-year award of \$23,432,430
AMOSTRA	Private Sector	Diagnostic Sample Transportation	Final Stages of Procureme nt	\$594,012	\$2,000,0 0	

# How does localization fit into the larger supply chain context and strategy for Mozambique?



Forecasting & Supply Planning



Sourcing & Buying



Customs Clearance



National Storage Level



In-Country Transport



Sub-National Storage Level



Last Mile Delivery

PSM supports with TA

USAID
procures
~half of the
country's
commodities,
while ¾ of
ARVs come
from GF

Customs
clearance
responsibilities
are shared
between PSM
FO (requests
waiver), MoH
(grants waiver),
and 3PL
(Clearing agent)

5 regional warehouses function as the central level and are managed by CMAM with PSM TA Long Haul distributions are carried out by PSM; future plans for this to be absorbed by CMAM

11 provincial
warehouses and
additional district
warehouses are
owned and
managed by GoM
and supported
with PSM TA;
these will
eventually become
Intermediary WHs

Last Mile
Deliveries are
done through
PEPFAR
bilaterals
(CHEGAR or
AMOSTRA for
lab)

# Local mechanisms in Uganda

Mechanism Name	Туре	Function	Current Status	COP 20 Funding	COP 21 Funding	Future Status
MAUL	Local Partner	Procurement Management for PNFP sector	Active			
JMS	Local Partner		Active			
NMS	G2G	Procurement, warehousing and distribution	Assessment phase		\$100,000	Implementati on planned for COP22

# How does localization fit into the larger supply chain context and strategy for Uganda?















Last Mile Delivery

PSM's Field office supports the local Procurement Service Agent with Technical Assistance.

GHSC-PSM staff apply for and ensure that waivers from MOH, Manufacturers representative, National Drug Authority are obtained before shipment. JSM makes deliveries directly to the SDPs on a bimonthly basis. JSM delivers to Private For Profit, Private Not for Profit, and Public facilities on behalf of NSM for TO1 commodities.

— 10 Guiding Principles for Localization in Supply Chains



- OHA views localization as a component of supply chain diversification, and a pathway to resilient and self-reliant supply chains.
- 2 Localization should be designed in a way that bolsters country ownership and governance of the supply chain.
- Localization should be considered within the broader context of regional opportunities for supply chain coordination.
- 4 Country context and supply chain maturity determine readiness for localizing each supply chain function.
- 5 Supply chain localization requires long-term strategy and multi-year investments.

- 6 Localization of supply chain functions requires risk planning and mitigation investments.
- 7 Donors must consider and internalize cost and performance tradeoffs.
- Functional areas for localization have unique limitations and considerations.
- Sub-national partners should be engaged in localization efforts.
- Localization efforts must be coordinated across health areas.

# — Developing a Localization Strategy



# **Assessing Readiness:** Before proceeding with a G2G, Local Partner, or other Bilateral award, a Mission must consider

## Mission Resourcing

- Staffing
- Management Capacity
- Monitoring and Evaluation

# Performance & Risk Management

- Risk Management Plan & Assessment
- Monitoring and Evaluation Plan
- Third Party Monitoring (TPM)
- Data collection and flow

## Local Partner Capacity

- Financial systems
- Written policies and procedures
- Needed capacity building

# Whole-of-Supply-Chain Impacts

- Supporting TA from other IPs
- O Division of roles and responsibilities
- Transition timeline
- Alignment with National Supply Chain Plans

# Take-Away: building a plan customized to your country

- Highlighting the most realistic options for optimal supply chain success, appreciating country context. Promoting the interconnectivity of all segments of the supply chain, local or international, and supporting comprehensive start-to-finish service options.
- This can be interpreted as a blend of local and international service providers, or along both ends of the spectrum. SCH has a pragmatic approach of supporting high impact supply chain system updates as they make sense in each respective country.
- Localized customizations per country are based on available competitive local options, governance capacity, and optimized supply chain efficiencies.





# RESEARCH TECHNICAL SESSION

Alexa Edmier, MPH Ashley C. Lima, PhD, MPH

# **SESSION ROADMAP**

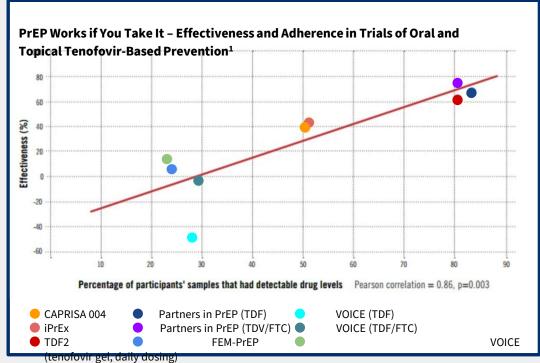
- I. Introduction to OHA Research Division
- II. Local partner activities, resources, and opportunities across OHA Research Division projects
- III. Policy and guidance updates for biomedical HIV prevention tools

# **OHA RESEARCH DIVISION** WHO WE ARE AND WHAT WE DO

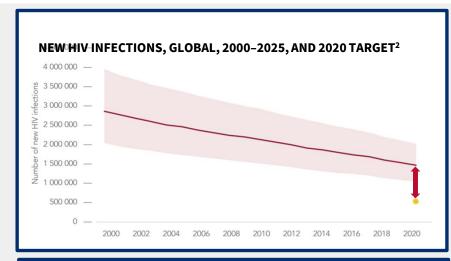
### THE CASE FOR EXPANDED PREVENTION

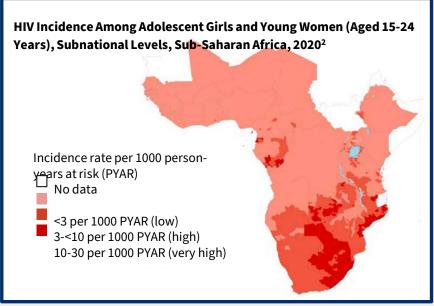
**Proposition** became newly infected with HIV in 2020

- Women and girls accounted for 63% of all new HIV infections in SSA
- "Success" of a product is not just the success of a program; need prevention product choices that fit into lifestyles



<sup>1</sup> Salim S. Abdool Karim, CAPRISA, 2016



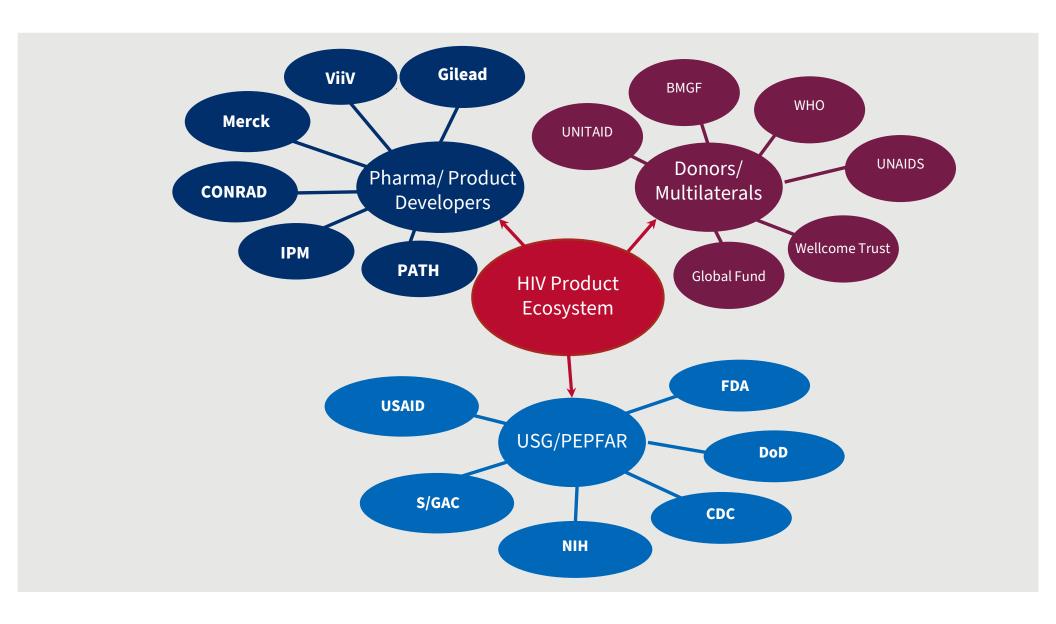


<sup>&</sup>lt;sup>2</sup> UNAIDS epidemiological estimates, 2021 (https://aidsinfo.unaids.org/)

# **OHA RESEARCH DIVISION END-TO-END MODEL**



Cross-Cutting: Policy, Advocacy, Strategic Partnerships, and Capacity Strengthening



# PEPFAR'S REIMAGINED STRATEGIC DIRECTION

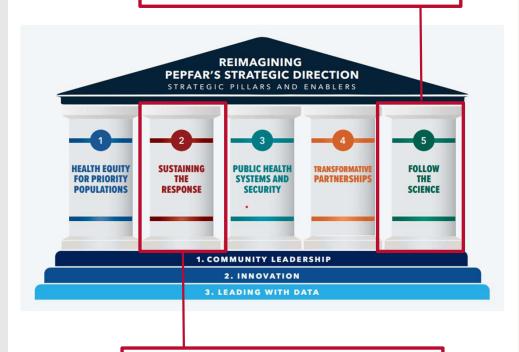


**Localization:** supporting the increase of technical, institutional, and service delivery capacities of local partners... to strengthen their ability to lead programming and absorb increased support from PEPFAR, governments, and other donors.

**Research:** investing in the scale-up of cutting edge behavioral, & implementation science to bend the curve on new infections

"

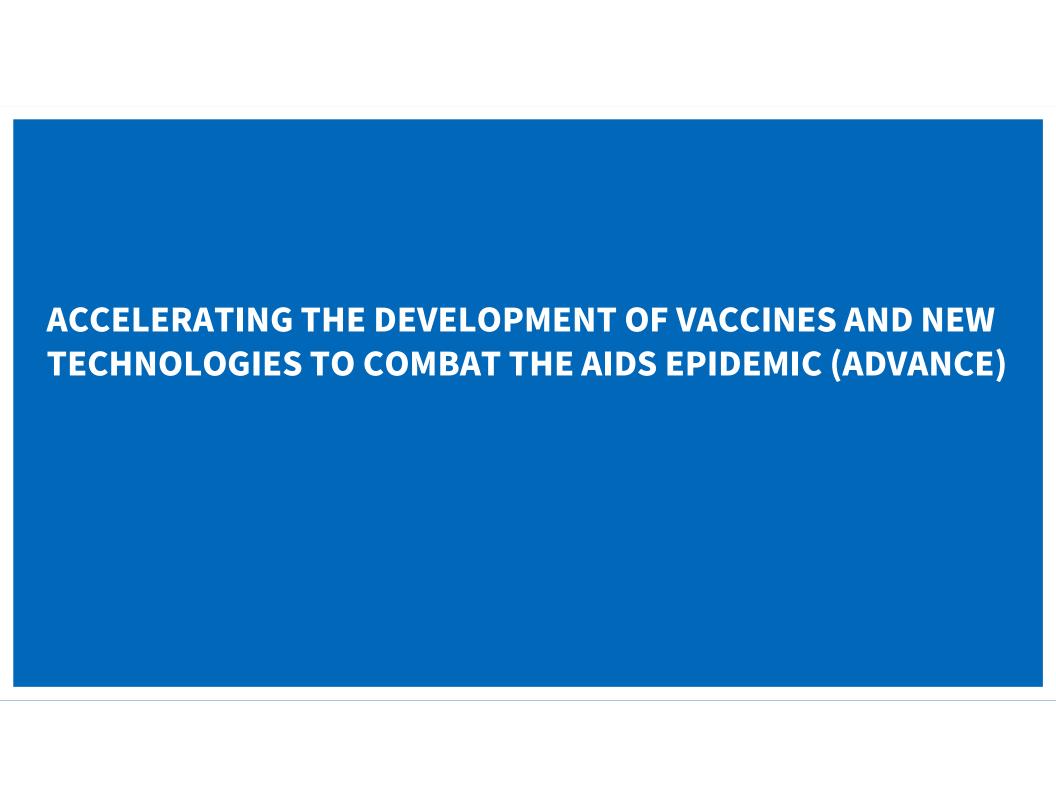
PILLAR 5: Follow the Science – Innovation



PILLAR 2: Sustaining the Response – Localization

# LOCAL PARTNER ACTIVITIES, RESOURCES AND OPPORTUNITIES ACROSS RESEARCH DIVISION PROJECTS

OHA/Research Division Project Highlights: ADVANCE, MATRIX, MOSAIC, CASPR



# **ADVANCE SNAPSHOT**

ADVANCE is dedicated to the development of safe and globally effective HIV vaccine and biomedical prevention products that are available and accessible for populations at risk of infection with leadership by African and Indian stakeholders.



**Strategic Area 1:** Translational research and observational epidemiology studies



Strategic Area 2: Clinical development and experimental epidemiology studies



**Strategic Area 3:** Capacity strengthening for HIV vaccine and biomedical prevention research



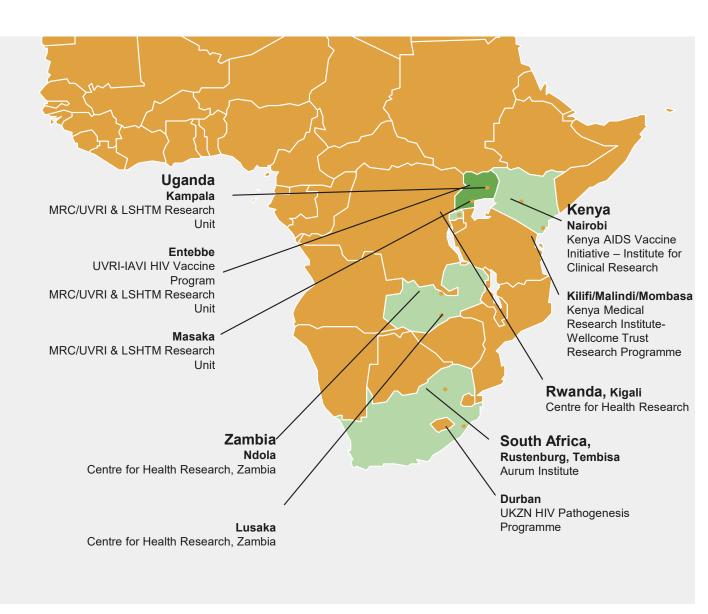
Strategic Area 4: Translational development



Sustainable and self-reliant CRC network African Translational Research Consortium Safe and globally effective HIV vaccine

# HIGHLY EXPERIENCED NETWORK OF CLINICAL RESEARCH CENTERS (CRC)

- Scientific capacity building integral to every trial
- Clinical trials conducted at highest international standards with stateof-the-art clinics, pharmacies & labs to establish technical platforms
- Foundation of research preparedness and community engagement
- Application of epidemiology and engagement ensuring most at-risk populations can be included in clinical trials
- Access to diverse populations



# **ADVANCE RESOURCES FOR LOCAL PARTNERS**

- Well positioned CRC partner network
  - To improve the sustainability of advanced research capacity
  - Possibilities for collaborations on research projects
- Building a Trusted Research Environment
  - A cloud-based platform to host and provide access to data
  - Compliant with General Data Protection Regulation (GDPR)
  - Secure and auditable
  - May be open to data from new partners in 2nd half of 2023



# MATRIX SNAPSHOT

Preclinical and early clinical biomedical HIV prevention research that prioritizes the most promising products with the greatest potential impact

Early Stage Product R&D Participatory Research for Product R&D (D2) Engagement of those who are most impacted by the lack of HIV prevention options to inform decisions about product design and portfolio priorities

Sustain development research of later-stage products with demonstrated safety, efficacy and improved end-user acceptability

Late Stage Product R&D

Local R&D Capacity Strengthening (CaSE)

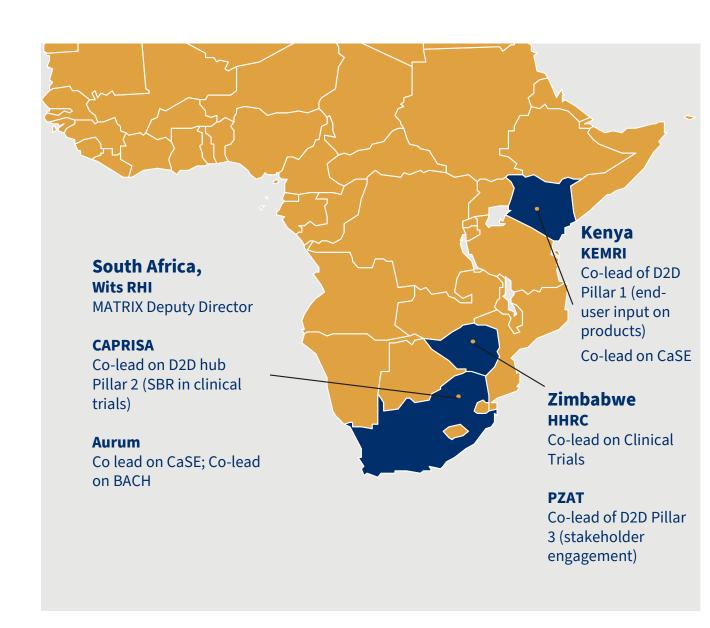
Expand equitable research partnerships and collaborations among local organizations, scientists, and other implementers

Innovative designs of clinical research that include African women in earlier stages of testing to provide evidence for safety and efficacy of new products and support their expedited approval

Clinical Trial Design for Product R&D Business Case for R&D (BACH) Investment decisions are informed by business plan development, regular assessment of the global HIV prevention landscape and rigorous evaluation of technical achievements

# LOCAL LEADERSHIP AT ALL LEVELS

- MATRIX is co-lead by both North and South
- Research protocols are created by both North and South
- PIs are from both the North and South
- Increasing capacity to initiate product R&D activities in the South



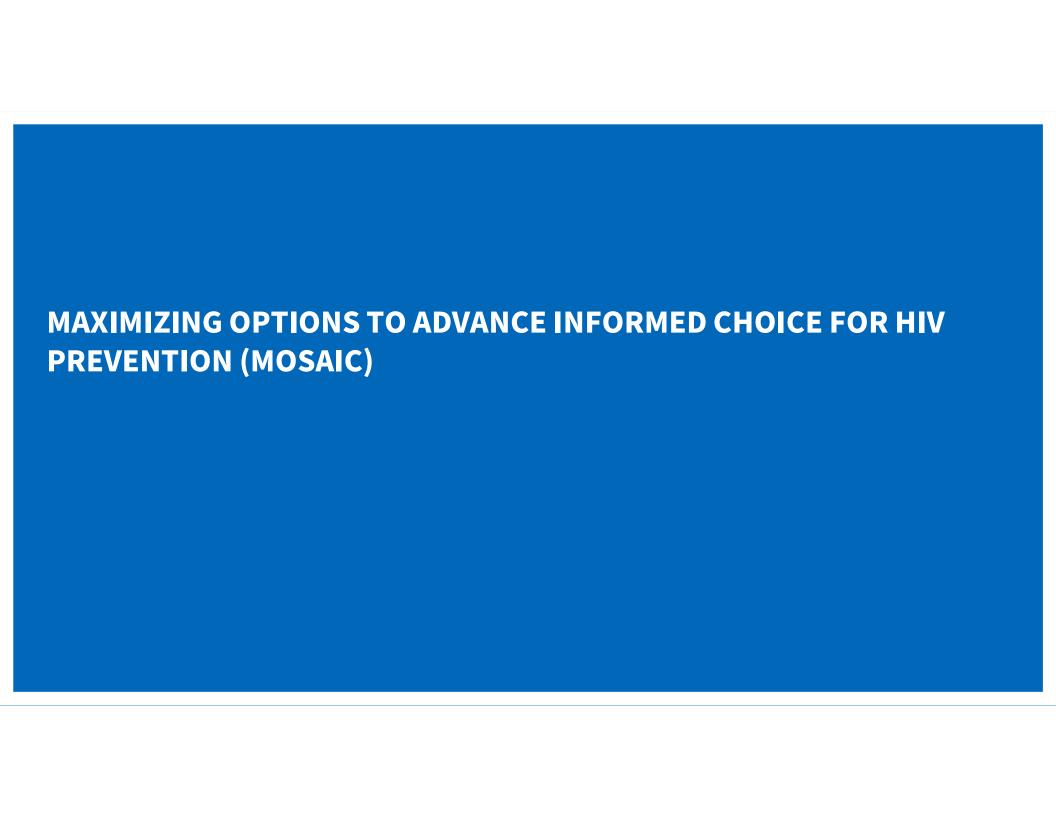
# MATRIX OPPORTUNITIES FOR LOCAL PARTNERS

### MATRIX is anticipating publication of 3 requests for applications in 2023

- Technology Accelerator
   Goal: to support innovative, potential 'game changing' technologies for HIV prevention and MPT indications by providing seed funding for feasibility of the technology
- Integrated Special Projects RFA
   Goal: to support focused project that add value or enhance existing research infrastructure in SSA
- Case Hub Fellowship Program (South Africa, Kenya, Zimbabwe candidates only)

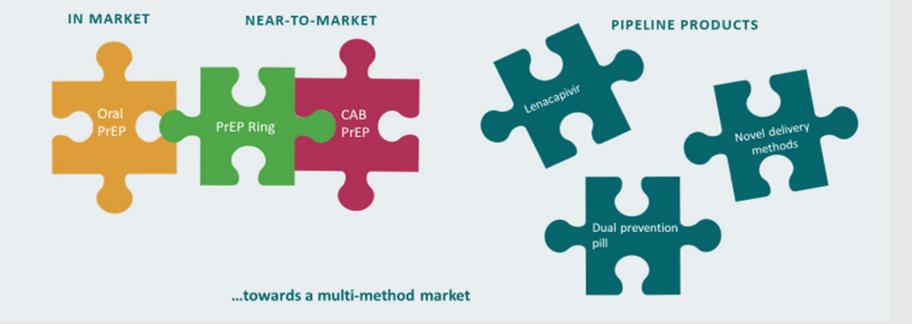
  Goal: to cultivate a self-sustaining network of African research leaders in HIV prevention research by supporting capacity strengthening in mid-level and early career scientists

Does your organization have opportunities to expand MATRIX? If so, the MATRIX team wants to hear from you! gh.oha.matrix@usaid.gov

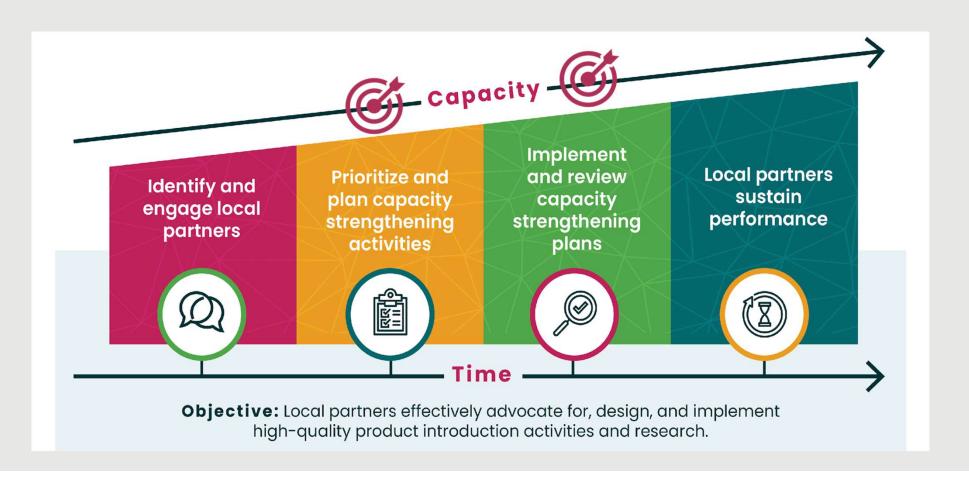


# MOSAIC's goal is to accelerate access to new products

MOSAIC works to accelerate and expand introduction of new HIV prevention products, including those in and near to market, and to lay the groundwork for introduction of those products in the research pipeline.

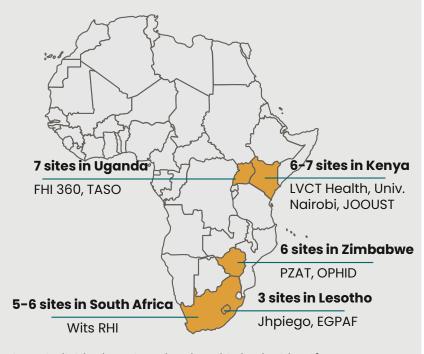


## MOSAIC CAPACITY STRENGTHENING FRAMEWORK



### **MOSAIC's CATALYST STUDY AND LOCAL PARTNER SPOTLIGHT**

- The **CATALYST Study** is a multi-country implementation science research study under the MOSAIC project, a 5-year global project funded by PEPFAR through USAID, led by FHI360
- **Study Goal:** The overall study goal is to characterize and assess the implementation of an enhanced service delivery package providing informed choice of PrEP products among women\* and AGYW
- Informed Choice: oral PrEP, PrEP Ring, CAB PrEP
- **5 Countries:** PEPFAR/USAID delivery sites in Kenya, Lesotho, South Africa, Uganda, Zimbabwe
- Local Partners: LVCT Health, PZAT, TASO, Wits RHI
- Objectives:
  - Facilitators and barriers of the implementation process
  - Patterns of use and effectiveness: acceptability & adherence, continuation/switching/discontinuation, prevention effective use
  - Clinically relevant indicators: rates of infection and drug resistance



<sup>\*</sup>For this study, the term "women" is inclusive of individuals assigned female at birth of any gender identity or individuals assigned male at birth who identify as women.

#### SNAPSHOT OF MOSAIC'S CAB PREP WORK ALONG THE INTRODUCTION PATHWAY

Policy, Plans & Costing

Supply Chain & Market Development

Service Delivery

Uptake & **Effective Use**  Monitoring & Evaluation

Cross-Cutting Activities

Global guidance & national guidelines

Contributing updates to WHO PrEP Implementation Tool, developing template guidelines for CAB PrEP, supporting adoption of national guidelines for CAB PrEP, integration with PMTCT and FP guidelines

Implementation plans & national strategies

Developing implementation plans and integrating CAB PrEP into national strategies, including support for target setting and forecasting (PrEP-it)

Costing

Conducting costing studies and analyses to inform implementation planning and budgeting

Market shaping

Contributing to market shaping efforts to address supply-side barriers and global demand

Demand forecasting

Conducting analyses for demand forecasting

Private sector

Developing private sector engagement roadmap

Supply chain

Assessing product stockouts, supply chain readiness

Implementation research

Conducting studies to assess implementation, acceptability, choice, uptake, patterns of use, prevention effective use, and cost; strengthening integrated and clientcentered service delivery through quality improvement collaborative

Provider training/job aids/ counseling materials Developing and integrating

CAB PrEP into national PrEP curricula, job aids and counseling materials

Research and program collaborations

Collaborating to identify common study indicators, pregnancy registry study; rapid data sharing to inform program scale-up

End-user engagement

Implementing strategy to meaningfully engage potential end-users

Positioning Strategy

Expanding PrEP positioning strategy to include providers and key influencers

Demand generation strategies & tools

Providing technical guidance on integration of CAB PrEP into demand creation national strategies and integrating CAB PrEP into demand creation tools, including the HIV Prevention Ambassador Training

Resistance surveillance

Supporting inclusion of CAB PrEP in HIV drug resistance surveillance platforms

Routine M&E

Assessing feasibility and acceptability of novel PrEP indicators for multi-product M&E, supporting system improvements/integration

Laboratory strengthening Increasing capacity for HIVDR testing

Civil society engagement Developing and strengthening civil society partnerships, engagement, and advocacy

Global collaborations Building and strengthening global collaborations with programs, networks, product developers, and funders

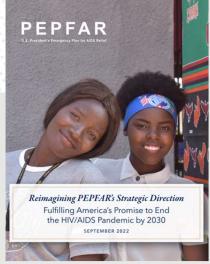
Situation analyses Conducting value chain situation analyses to build on lessons learned from oral PrEP to inform rollout of CAB PrEP

Capacity strengthening Strengthening local partner capacity to design and implement biomedical prevention product introduction activities and research

Evidence & Resources Synthesizing and sharing CAB PrEP evidence and resources

### LEVERAGING MOSAIC TO INFORM PEPFAR PROGRAM PLANNING





- Address research gaps prioritized by the WHO: where people
  prefer to access PrEP; understand how people choose and switch
  safely between PrEP options; provide further data on safety
  among pregnant and breastfeeding people; monitor drug
  resistance and testing approaches; and identify service delivery
  packages for populations and geographies not included in the
  RCTs (such as sex workers and people who use drugs)
- Inform country operational planning: MOSAIC HQ has dedicated LOE to provide light technical assistance to non-MOSAIC countries regarding new product introduction, e.g. how to conduct a value chain situational analysis; provide materials to inform policy development, etc.
- Support PEPFAR's 5x3 Strategic Direction: Addressing key forward-looking implementation questions and rapidly translating findings into scaled-up effective and cost-efficient HIV programs, centering local leadership and ensuring AGYW receive evidencebased, equitable, and people-centered prevention services



### **CASPR SNAPSHOT**

CASPR is an Africa-centered network dedicated to advancing advocacy, policy, regulatory, communications, and community engagement efforts that help accelerate biomedical HIV prevention research.

# Advocacy Network & Policy Engagement

Strengthen and expand an informed, action-oriented global advocacy network to support the HIV prevention research agenda while developing and advocating for policies that support efficient and ethical development, introduction and use of new HIV prevention options.

#### Research Translation

Strengthen sharing & translation of research into policies & practices to ensure support for a research agendas that reflects stakeholder needs & interests.

#### Research Preparedness

Ensure that rights & interests of trial participants, eventual users & communities are represented & respected throughout the process of research to rollout.































## CASPR RESOURCES FOR LOCAL PARTNERS

#### Engage platform

Online learning platform for peer-to-peer resource sharing, collaborative learning, and joint strategy development

#### Advocates' Network

Electronic network for organizations and individuals interested in receiving timely updates about developments in the biomedical HIV prevention field

#### Px Pulse

Monthly podcast using interviews, discussion and first-person reflections to explore vital topics confronting the field of HIV prevention research



# POLICY AND GUIDANCE UPDATES FOR BIOMEDICAL PREVENTION TOOLS

## WHO RECOMMENDED PREVENTION PRODUCTS

- Oral pre-exposure prophylaxis recommendation (2016)
  - Oral pre-exposure prophylaxis (PrEP) containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches (strong recommendation, high certainty evidence).
- **Dapivirine vaginal ring** recommendation (2021)
  - The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches (conditional recommendation, moderate-certainty evidence).
- Long-acting injectable cabotegravir recommendation (2022)
  - Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (conditional recommendation; moderate certainty of evidence).

# WHO IMPLEMENTATION GUIDANCE FOR SIMPLIFIED AND DIFFERENTIATED SERVICE DELIVERY OF PRE-EXPOSURE PROPHYLAXIS (PrEP)

- **PrEP Services:** People who want to use PrEP should have access to PrEP. 1) PrEP provision locations, 2) PrEP service providers, 3) PrEP service frequency and 4) PrEP service packages should be evaluated and optimized to promote access.
- Long-acting PrEP injections (Cabotegravir): The long-acting PrEP injection known as
  Cabotegravir or CAB-LA has been added to WHO guidelines as a prevention option for people at
  substantial risk of acquiring HIV.
- **Oral PrEP dosing frequency:** People assigned male at birth can take a double dose of oral PrEP 2-24 hours before sex, another dose 24 hours after the first dose and a fourth 48 hours after the first dose. People who don't qualify for the event driven PrEP, can take the PrEP pill every day for seven days after having sex.

# WHO IMPLEMENTATION GUIDANCE FOR SIMPLIFIED AND DIFFERENTIATED SERVICE DELIVERY OF PRE-EXPOSURE PROPHYLAXIS (PrEP)

- HIV self-testing: HIV self-testing should be offered to increase the frequency of testing and
  reduce the need for more clinic visits, but positive HIV self-tests should be confirmed by inperson testing at the clinic.
- **Hepatitis B & C:** When possible, it's important to test for both Hepatitis B and C within 1-3 months after oral PrFP initiation.
- **Kidney Function:** Routine testing for kidney function is no longer required for oral PrEP users who are 30 years and younger.

# WHO PREFERRED PRODUCT CHARACTERISTICS (PPCs) FOR MONOCLONAL ANTIBODIES (mAbs) FOR HIV PREVENTION

- **Indication of Use:** Prevention of HIV-1 infection in HIV-negative individuals, along with neonates and infants with HIV exposure
- **Target Populations:** Individuals and their sexual partners who are at high risk of HIV infection. Populations include, but are not limited to:
  - MSM, FSW, PWID, and others
  - Serodiscordant couples
  - Neonates and infants with HIV exposure
  - Pregnant and breastfeeding women in high prevalence settings
- Access and Affordability: Costs of products and health care delivery should be affordable and cost-effective in LMICs



Program Analyst

























QUESTIONS?













Program Analyst Vacant

