

CaSE

MATRIX Investigators Meeting

The Program, The Fellows, The Plan
August 29, 2023

Pholo Maenetje



Agenda

- Introduction
- CaSE Fellowship Program
 - Addressing critical skills shortages
 - Strategy
 - CaSE Tracks Overview & Progress
- Global South Hosts
- Prospects

Introduction

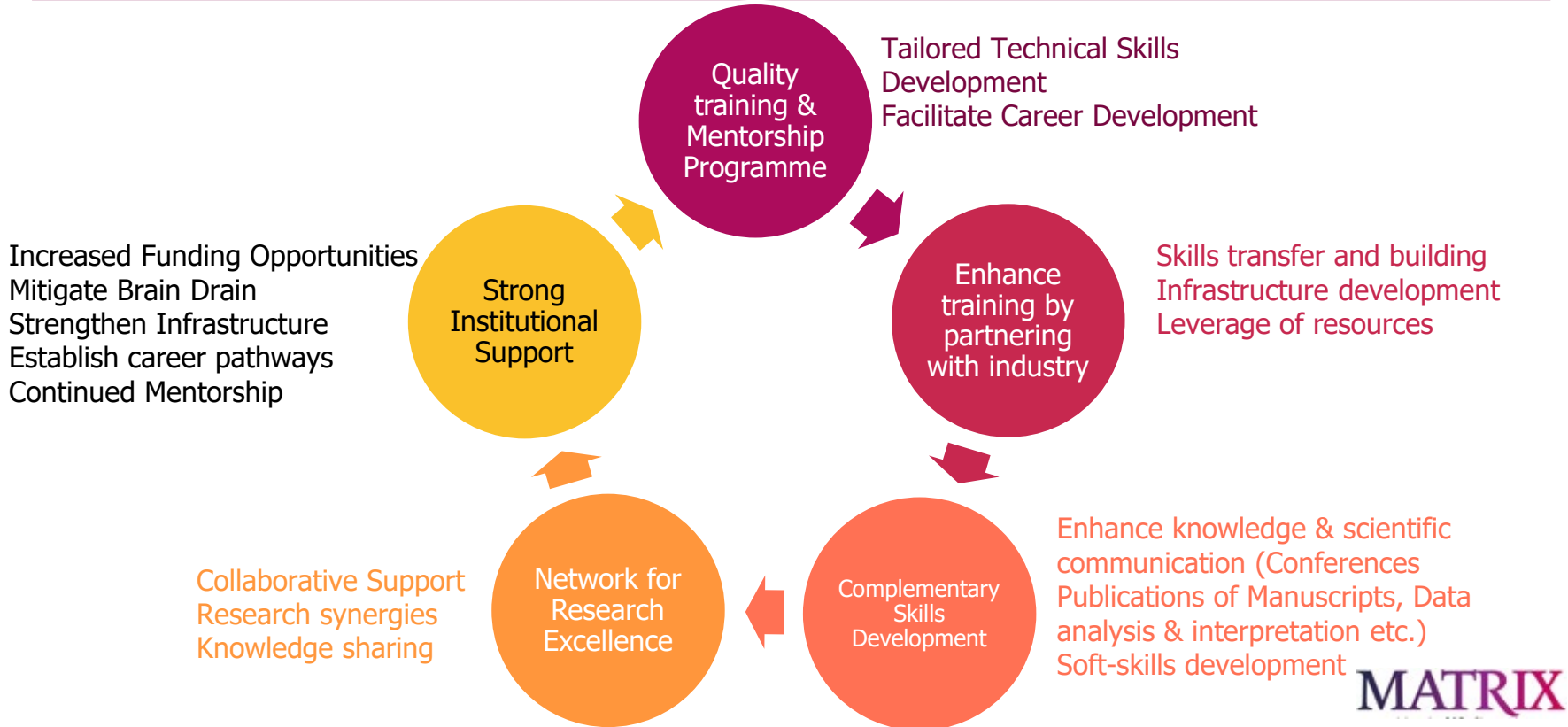
- Pharmaceutical R&D have largely taken place in the Global North (GN)
- Challenges in the Global South (GS):
 - Poor access to infrastructure
 - Scarcity of enabling technology platforms
 - Lack of a critical mass of skilled scientists
 - “Brain-drain”
- *There is a need to create locally networked African research scientists to contribute to the development of HIV prevention products*

Winks, S., Woodland, J.G., Pillai, G. et al. Fostering drug discovery and development in Africa. *Nat Med* **28**, 1523–1526 (2022).

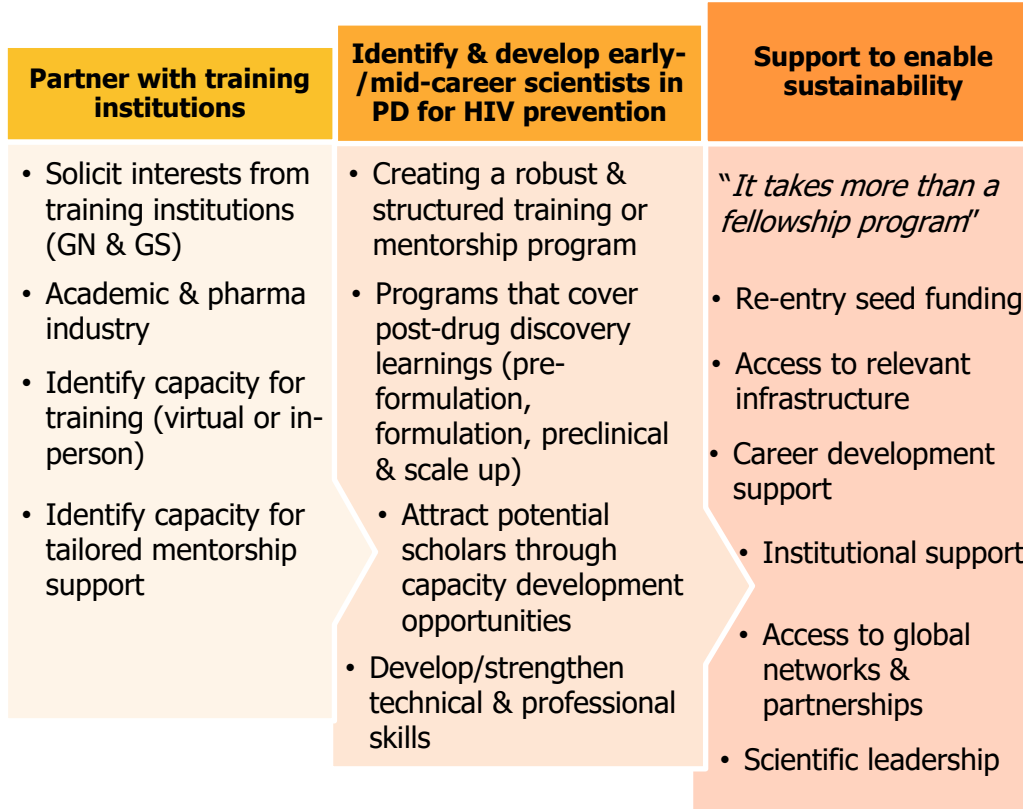
CaSE Fellowship Program

The overall goal of the Capacity Strengthening and Engagement (CaSE) Fellowship Program in MATRIX is to build technical skills of early and mid-level scientists in sub-Saharan Africa (SSA), to enhance local capacity for HIV prevention

Addressing critical skills shortages



CaSE Strategy



CaSE Strategy: Tracks overview

Track 1

- Short-term e-learning courses (*variable timelines*)
- In-collaboration with MATRIX partners & various training organisations
- Learnings focused on early-stage product development & HIV prevention
- E.g., biostatics, regulatory, drug development process

Track 2

- Short-term in-person or virtual mentorship (*3-6 months*)
- In-collaboration with MATRIX hubs/partners
- Learning focused on social and behavioural research, stakeholder engagement, market analysis, economic analysis, etc.

Track 3

- Long-term training which includes online & in-person mentorship (*~18 months*)
- In-collaboration with MATRIX PDs & Global-South research institutions or pharma companies
- Learnings to include a research project, grant writing, publication, scientific leadership

Overview of 2023 CaSE Scholars and Fellows

Track	Course	Duration	Applications received	Applicants selected	Status
Track 1	The Drug Development Process	4 months	9	Total: 7 <ul style="list-style-type: none"> Kenya: 3 South Africa: 2 Zimbabwe: 2 	Ongoing Anticipated to launch early October
	Introduction to Data Analyses and the Drug Development Process	4 months	10	Total: 4 <ul style="list-style-type: none"> Kenya: 4 	Ongoing Anticipated to launch early October
	Product Development and the Regulatory Process	4 months	20	Total: 14 <ul style="list-style-type: none"> Kenya: 3 South Africa: 2 Zimbabwe: 9 	Ongoing Anticipated to launch early October
Track 2	BACH Scholar	7 months	13	Total: 1 <ul style="list-style-type: none"> Zimbabwe: 1 	Ongoing Contract pending approval
Track 3	HIV Prevention Product Development Fellowship	24+ months	13 (in process) 4 shortlisted	pending	Ongoing Selection in process

Track 1: e-Learning courses

In partnership with the University of Wisconsin, Madison's Department of Pharmacy

Drug Development Process

- Overview of drug development process
- Small molecules (Biologics & biotherapeutics)
- Substance characterization
- Stages of clinical development
- FDA IND

Regulatory Process

- Describe the laws and regulations associated with drugs, biologics, and medical devices in the US and African continent.
- Analyze the regulations that impact drug and biologics development, dietary supplements, medical devices, and diagnostics.

Data Analysis

- Identify relevant software platforms and databases used in drug discovery/development
- Analyze dose response curves and other large datasets
- Conduct PK/PD data analysis projects using industry-standard software packages.

Capstone Project

Track 1: CaSE 2023 Fellows

Kenya



Alex Mwangi
MPharm
County Govt. of Laikipia



Benjamin Koeh
MPH (in progress)
KEMRI



Davies Otieno
MMed, MPharm
University of Nairobi,
Kenyatta Hospital



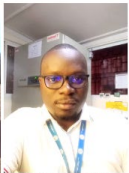
Ferdinand Odunga
PhD Immunology
KEMRI



Florence Wambui
BPharm
Oximio Limited



Joseph Ngugi
Masters
Nyahururu County
Referral Hospital



Kelvin Wandera
BPharm
Impact Research &
Development
Organization



Mercy Onyango
MPH (in progress)
KEMRI



Scholastic Wanjiru
BPharm
KEMRI



Walter Nyagah
Bachelors
Equitech Futures

Zimbabwe



Admire Nyika
MBA, MPharm
Avacare Health



Anesu Venge
BPharm
Alowell Medical
Investments



Caroline Murombedzi
BPharm, MPH
HHRC



Elton Dangare
MPharm Biotech, DPhil
(in progress)
Chinhoyi University of
Technology



Rosemary Chigwanda
PhD
University of Zimbabwe



Rumbie Nyamuriya
MPharm
Datlabs



Samson Saruchera
Msc
AIDS Health Foundation,
Zimbabwe



Tendai Mabhumbo
MPharm
Wild Leaf Farms

South Africa



Andile Mtshali
PhD
CAPRISA



Boitumelo Molefe
Bachelors
Aurum Institute



Givemore Mushayi
Masters
Innovata
Pharmaceuticals



Rito Shiburi
Bachelors
Clicks Retailers

These Scholars will join the CaSE Track 1 cohort.

2022 Track 1 Scholars, n = 21

2023 Track 1 Scholars, n = 25

Total Track 1 Scholars to date, **n = 46**

Track 1: Challenges and Solutions

Challenge

01

Licensing of the data analysis course delayed

02

Unexpected drop out of regulatory consultant for the African-setting Regulatory course

03

Misalignment of course preferences vs needs assessment findings

Solution

01

Using alternative software options that are equally industry-relevant

02

Engaging and assessing 7 alternative options

03

Gauging interest in the courses that UWisc offers and other training opportunities with a survey

Track 2: Short-term Fellowships

D2D Hub

- RFA: May 2022
- Two candidates enrolled
- Started: Nov 2022 and ended April 2023
- Duration: 5 months
- Renewed May 2023 to Dec 2023
- Progress, milestone & outcome evaluation conducted every 3 months with CaSE, mentors and Scholars

BACH

- RFA: May 2023
- 13 applications; 1 candidate enrolled
- Contracting process underway
- Anticipated start: August (pending approval of contract)
- Duration: 7 months
- Progress, milestone & outcome evaluation anticipated to be every 3 months with CaSE, mentors and Scholar

Track 2: The Fellows

D2D Pillars 1 & 2



Wanzirai Makoni
PZAT
Mentor: Ali Minnis

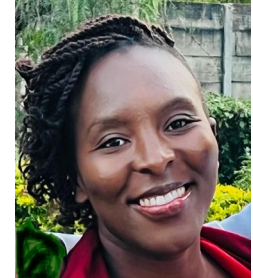


Njeri Wairimu
KEMRI
Mentor: Kenneth Ngure

Ongoing activities:

- Conduct 2nd round of design consultation and contributing to journey maps
- Create and implement market segmentation surveys
- Launch of Rapid Response Network
- Develop MATRIX-002 qualitative guide

BACH Economic Evaluation Team



Tsungai Mhembere
University of Zimbabwe
Mentors: Gabriela
Gomez, Sergio Torres
Rueda

Planned activities:

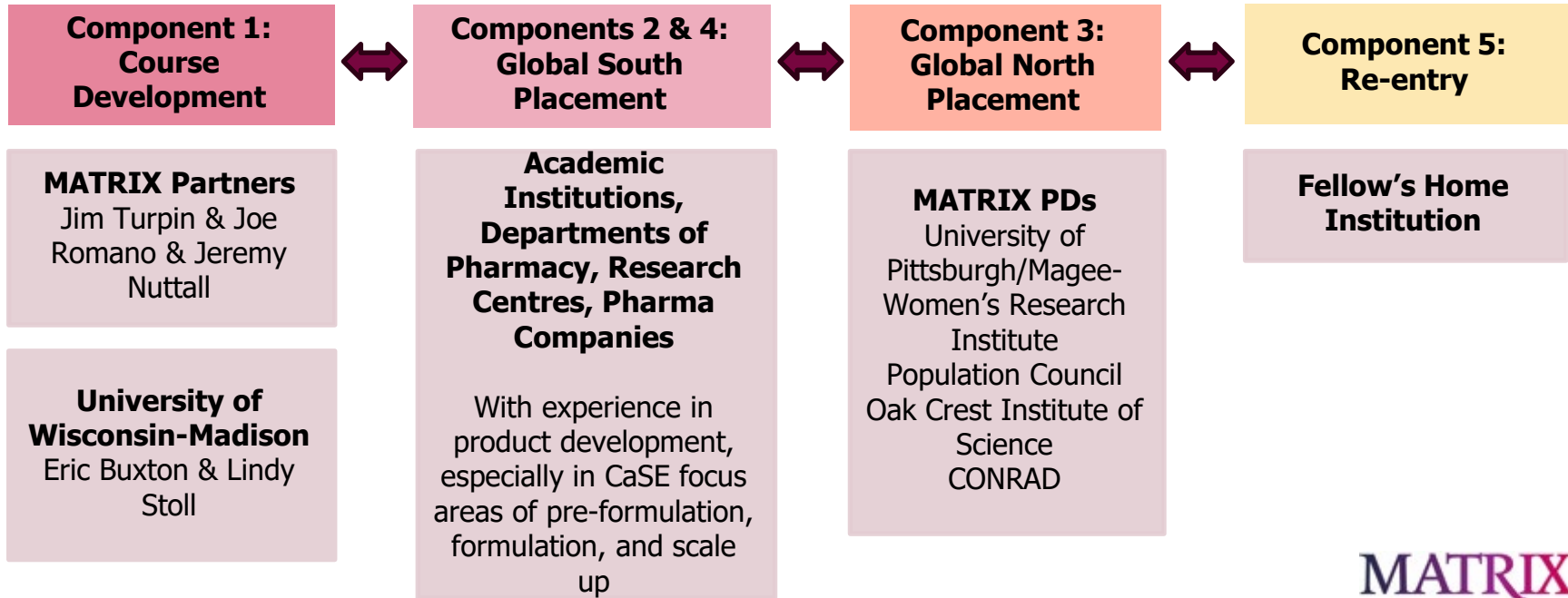
- Define possible delivery pathways for products in development
- Conduct delivery costs estimates to feed into PD's early planning and clinical development
- Explore potential cost effectiveness for MATRIX HIV prevention products

Track 3: Long-Term Fellowships

Component 1: E-learning Course [1 month]	<ul style="list-style-type: none">• Self-paced, 40-50h e-learning course on the basics of theoretical product development with a focus on HIV prevention. To be completed before starting Component 2
Component 2: Global South placement [3 months]	<ul style="list-style-type: none">• Hands-on practical work in Global South lab theoretical learning with mentorship
Component 3: US-based placement [6 months]	<ul style="list-style-type: none">• Hands-on practical work in the lab with MATRIX PDs, specifically on HIV prevention products to gain specific skills
Component 4: Return to Global South placement [14 months]	<ul style="list-style-type: none">• Hands-on practical work in Global South lab
Component 5: Re-entry	<ul style="list-style-type: none">• Continued CaSE Mentorship• Proposal writing and opportunity to apply for small project funding

Track 3: Long-Term Fellowships

Collaborators

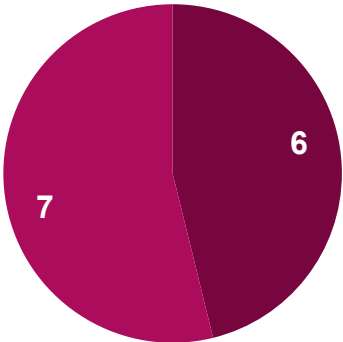


Track 3: YR2 2023 Timeline

	Q1	Q2	Q3	Q4
Track 3				
Cohort 1 RFA release				
Cohort 1 Scoring and selection				
<i>Component 1</i>				
Course Development				
Implementation				
Evaluation				
<i>Component 2</i>				
Host identification				
Host contracting process				
Implementation				
Evaluation				

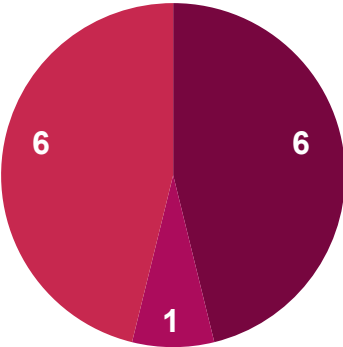
Track 3 (Distribution of all applicants, pending selection, n=13)

Gender



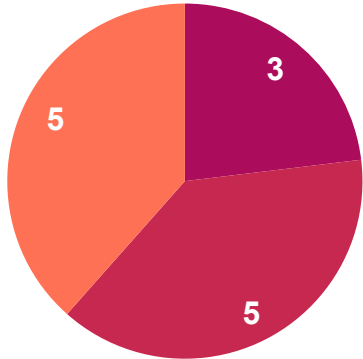
■ Male ■ Female

Country of residence



■ Kenya ■ South Africa ■ Zimbabwe

Education



■ Bachelors ■ Masters ■ PhD ■ Post-doc

Refined focus for the RFA

Based on our assessment of the applicants, we honed on the skills that would make a successful candidate and have reflected this in a revised RFA

Original RFA	Updated RFA
We casted a wide-net with the specialty that was inclusive of many disciplines (including MMed, immunology, biology, chemistry, etc.)	Given the specific skills needed for placements, we believe that a Fellow with a strong pharmacy education would be best suited; either in pharmacy or industrial pharmacy
We asked for wet lab skills that were inclusive (e.g., biology, chemistry, etc.)	We are honing on those who have had pharmaceutical lab experience, in particular those who may have had hands-on experience with pellets, gels, films, etc. would be a bonus
We were also broad in looking for product development experience, and so further specified	We are looking for someone who has done research and development in product development and preferably in HIV/STIs

Track 3: Challenges and Solutions

Challenge

01

Low-response rate for the application and no representation from SA

02

Alignment of timelines components

03

Finding additional potential hosts

Solution

01

Social media platforms and refining the RFA to identify suitable candidates

02

Transition period and activities between components

03

Consideration of Pharma companies and direct outreach to university pharmacy departments and pharmacy councils. Using a snowballing strategy with promising candidates.

Prospects

Track 1

- Strengthening North-South collaborations
- Leveraging more Global South training opportunities
- Being adaptive and response to learning needs of Scholars

Track 2

- Continuing to find opportunities with Hubs to offer learning opportunities that align with Hub activities and PD needs
- Offering Track 1 courses for Scholars that can complement Track 2 programs

Track 3

- Expanding placement opportunities to include industry partners
- Honing in on the profile of prospective candidates to ensure successful placements and matching
- Learning from launch the 1st cohort of Fellows and adapting the fellowship to Fellows' needs

Acknowledgements



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The contents in this presentation are those of the presenter and do not necessarily reflect the view of the U.S. President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development or the U.S. Government.

