Capacity Strengthening and Engagement (CaSE) Product Development Fellowship Program

Request for Application (RFA) # 2024-001

HIV Prevention Product Development
Track 3 Fellowship RFA

I. Opportunity Summary

The MATRIX Capacity Strengthening, Engagement, and Mentorship (CaSE) team seeks

applications for Fellows with interest in growing, gaining and refining technical skills and capacity to lead and inform pharmaceutical product development in HIV prevention and dual

prevention biomedical products on the African continent.

Biomedical (pharmaceutical) product development is a lengthy and complex process of

systematic steps required to bring a product to the market. It is defined as the full life cycle of

product development including early drug discovery, pre-formulation and formulation

development, pre-clinical animal testing phase, clinical trials, regulatory approval, manufacturing and launch, and post-market safety monitoring. MATRIX supports research and

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development of novel biomedical HIV prevention products that are in the pre-clinical and early

clinical development phases.

The CaSE Fellowship program aims to contribute to building the next-generation of African

product developers with expertise in the development of novel HIV prevention drug delivery

formulation technologies. The primary focus of the fellowship is the pre-formulation,

formulation and scale-up phases of product development. In addition to building skills in

product development, the Fellowship will provide guided mentorship with a range of experts

from both the Global South and Global North across the product development spectrum for the

development of funding applications and results dissemination.

CaSE invites aspiring post-graduate fellows who are seeking an exciting opportunity in

early-stage product development to apply for a game changing multi-country research training opportunity. Applications are open to those with research backgrounds in pharmaceutical

sciences and dedication to advancing product development for HIV prevention and MPTs.

All partners hosting have experience training and mentoring emerging scientists in product

development for HIV, contraception, STI prevention and other diseases. CaSE is excited to

welcome the 2023 – 2026 host institutions for the CaSE Fellowship Program. These hosts

include well-renowned academic and research institutions in product development and HIV

prevention.

CaSE RFA Track 3 Fellows v 1.0

Last updated: January 17, 2024

2

With North-West University's Pharmacy of Centre of Excellence for Pharmaceutical Sciences (PharmaCen) and Preclinical Drug Development Platform (PCDDP) (South Africa); the Magee Womens Research Institute (MWRI), University of Pittsburgh (Pennsylvania, USA); and CONRAD, East Virginia Medical School (Virginia, USA), CaSE will support up to 4 Fellowships that will begin in 2023.

About CaSE and MATRIX

This practical training component is part of the <u>CaSE Fellowship program</u>, sponsored by the Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and eXcellence (MATRIX) Consortium with funding through the United States Agency for International Development (USAID). MATRIX is designed to expedite research and development of products for the prevention of HIV in women (https://matrix4prevention.org). MATRIX is led (designated "the Prime") by Magee-Women's Research Institute, Pittsburgh, USA and Wits RHI, University of the Witwatersrand in Johannesburg, South Africa. MATRIX's scientific and operational priorities include equitable leadership and representation by stakeholders in East and southern Africa as well as the US, to advance products that meet the diverse HIV prevention needs of adolescent girls and young women, pregnant and breastfeeding women, and female sex workers in sub-Saharan Africa who face a disproportionate burden of HIV.

The CaSE Program focuses on enhancing product development skills from post-drug discovery through late-stage Phase 1 to support HIV-prevention product development in east and southern Africa. The vision for impact by the CaSE fellowship program includes increasing end-user product choice through products developed hand-in-hand with African researchers, policy makers, and regulatory authorities.

Representatives from the Aurum Institute (Johannesburg, South Africa), the Kenyan Medical Research Institute (KEMRI) (Nairobi, Kenya), the Public Health Institute (PHI) (California, USA), the MATRIX Consortium, and the hosting research laboratories will oversee the selection and interview process of the Fellows.

II. Key Dates

Summary of key dates:

Release of RFA	Monday, January 8, 2024
	(8:00am PT, 5:00pm SAST, 6:00pm EAT)

Applications due	Friday, February 23, 2024
	(8:00am PT, 5:00pm SAST, 6:00pm EAT)
Interviews scheduled for top round of applicants (virtually)	February 12 – April 12, 2024
Applicants notified of decision	End of April 2024, early May 2024
Estimated fellowship launch	June 3, 2024

III. Applicant Criteria

The program targets post-graduate candidates/researchers from the 3 specified countries (South Africa, Kenya, Zimbabwe). MATRIX will fund selected fellows to receive training to develop new research skills in product development for HIV prevention. Applicants should meet the criteria below:

- Must have a minimum of a postgraduate degree conferred within the past 4-10 years in the field of pharmacy (Drug delivery, Pharmaceutical Chemistry, Pharmaceutics, Pharmaceutical Technology, Industrial Pharmacy and related fields), formulation development and other related disciplines.
 - Graduate or doctoral students seeking funding to complete their degree program may be considered if there is alignment in scope and timeline with this program.
 - Master's degree holders (graduates with a Masters degree) are encouraged to apply if they meet all other requirements
- Must have a minimum of two years laboratory (bench-time) research and development experience in product development, preferably in the domain of HIV or other infectious diseases
- Previous experience in the formulation development of tablets, gels or films is an added advantage
- Must be currently employed/affiliated/hosted by an institution (for example: academia, research, industry or a science council) in Kenya, South Africa or Zimbabwe
- Must have agreement from the home institution to participate for all 24-30 months of this Fellowship, as demonstrated with a verifiable letter of support (this will be submitted through the application portal)

IV. CaSE Fellowship Program Scope and Components

The CASE fellowship program will provide financial support to applicants from South Africa, Kenya and Zimbabwe to acquire essential theoretical knowledge, technical and practical skills specific to HIV prevention product development through placements in pharmaceutical formulation and drug delivery laboratories in the 3 specified African countries and the US.

Fellows must be committed to return to their home institution for a minimum of one year after completion of the fellowship. Through written reports, fellows will be asked to demonstrate ways in which the experience gained during the training program is being applied to work conducted at their home institution.

The Fellowship program will include the following components:



- 1. **Component 1:** Online product development coursework for approximately 40 hours to build greater theoretical understanding of product development and components specific to the fellow's interest.
- 2. **Component 2:** A 3-month placement in a partner laboratory in South Africa, Kenya, or Zimbabwe for practical hands-on-training and additional theoretical learning.
- 3. **Component 3:** A short-term 6-9 month supervised hands-on practical lab training (bench-time) with a US-based product development group.
- 4. **Component 4:** Up to 12-month hands-on supervised lab training at a partner laboratory in South Africa, Kenya, or Zimbabwe

- 5. **Component 5:** Support for re-entry into their home institution with ongoing mentorship from CaSE/MATRIX. This component will consist of the following stages:
 - a. Preparation for re-entry: Fellows will work with their Global North and South mentors to create a progress report during Component 3 which highlights their current progress.
 - b. Proposal development: North/South mentors would work with the fellow to create a non-renewable, short duration proposal that follows the strict policies, guidelines, standards and review procedures. This proposal would provide funding support for the early and conceptual stages of the fellow's project that will be focused on some aspect of the product development pathway and justify the additional funds would be needed upon their return to their home institution.
 - c. Proposal review and approval: The proposal would be reviewed by a panel and funds will be allocated for the Fellow dependent on the review of their proposal.
 - d. Fund distribution 1 of 2: The first tranche (or ½ of the requested money) would be given to the Fellow upon return to their home institution such that those funds are available for use immediately upon arrival to the home institution.
 - e. Fund distribution 2 of 2: There will be two requirements in order to receive the 2nd tranche of funds: 1) completion of a comprehensive and acceptable progress report <u>and</u> 2) submission of a proposal to another external funding body (e.g., National Institutes of Health).

This program is intended to provide some flexibility in the program components and timeline depending on the needs and learning goals of the Fellow, the availability of the placement sites, and the logistics for completion of administrative requirements (e.g., obtaining visas).

V. Award Information

Up to 4 successful candidates will be selected for this fellowship. The number of awards is contingent on receipt of meritorious applications that are responsive to the CaSE mission and objectives and the availability of funding.

Fellowships will be awarded to an individual and are not transferable from one individual to another. Fellows can only be funded one time through this program.

Visa application costs, living stipend, health insurance, and travel and accommodation costs will be covered for the duration of the fellowship.

VI. Application Components

- 1. CaSE Track 3 Application (link):
- Applicant full curriculum vitae (CV)
- Institutional Letter of Support: The applicant should provide a letter of support from the home institution authorizing his/her study leave for the duration of the fellowship (24 months). This duly signed letter of support should be on institutional letterhead; (1 page max, please see <u>suggested outline</u> in the <u>Application Handbook</u>).
- Two letters of reference (1 page max), and their contact information, from those who
 can speak to your scientific background and how this Fellowship can benefit you and
 your career. One of these letters should include a reference from your PhD and/Postdoc
 supervisor and the other letter should be from a supervisor at your current institution or
 employer, on an official letterhead.
- 2. Provide responses to the following questions. As you provide responses to the questions, please ensure that you are responsive to the indicated word limit per question (responses exceeding the word count will not be reviewed).
 - 1. Please tell us about the current drivers of your work. In your response, you may choose to describe what motivates you and what led you to become involved in the work you do. (Maximum 200 words)
 - 2. Please summarize the main tasks you undertake in your current role and some highlights and/or challenges you face in your current work (Maximum 200 words)
 - 3. What are your future career goals and how do you see this training opportunity helping to achieve your long-term goals? (Maximum 200 words)
 - 4. Why do you want to participate in this training opportunity? In your response, please include details on whether there are specific skills or research methodologies that you would be interested to learn more about. (Maximum 500 words)

VII. Review Criteria

All applications will be initially screened by the CaSE team and ranked. Final selections will be reviewed with the MATRIX Prime partner, MATRIX product developer partners, and USAID.

The extent to which the applicant will help to advance the Fellowship aim of building capacity for HIV prevention and/or MPT product development in Kenya, Zimbabwe and South Africa will be based on the application package, the quality and depth of the responses received to the questions listed in the RFA, the letters of reference, letter of institutional support, and interviews among top applicants (in-person and/or virtual).

The review criteria described below will be considered in the review process:

- Academic and/or professional record:
 - o Is the applicant's academic, and research record of high quality? In addition to academic merit and strength of application, prior experience in product development (publications on formulated products /patented product) may be an additional evaluation criteria.
 - o Are the applicant's prior training and research experiences appropriate for this award?
 - o Do the short-answer responses and reference letters address the applicant's potential in contributing to the field of HIV prevention and/or product development?
 - o Is there evidence of the applicant's commitment to meeting the program objectives?
- Career development goals:
 - o Does the career development plan demonstrate a clear commitment to a research career in the LMIC setting and/or interest in HIV prevention?
 - o What is the likelihood that the applicant's career development goals will contribute substantially to HIV prevention and/or MPT product development?
- Environment & institutional commitment to the applicant:
 - o Is there clear commitment from the applicant's institution to ensure that a minimum of 24 months will be devoted directly to the program described in the application?
 - o Is the applicant's institutional commitment to the career development of the applicant appropriately strong?
 - o Is there assurance that the applicant's institution intends the applicant to be an integral part of its projects and research programs?

o Is the environment for scientific and professional development of the applicant of high quality?

Selected fellows will undergo regular performance reviews to maintain participation in the Fellowship program. This will be done at start, middle, and end of each component of the program. Additionally, the CaSE Program team may require check-ins on a quarterly basis to assess the progress of the Fellow.

CaSE seeks to promote diversity within its programs, recognize the scientific achievements of our diverse membership, and foster career development and advancement for individuals from underrepresented groups. CaSE encourages applicants of all backgrounds, irrespective of age, culture, ability, race, ethnicity, gender identity and expression, sexual orientation, marital status, religious affiliation or socioeconomic status to apply.













