

BHP undergoes a successful EMA Inspection for the HPTN 084 Study



BHP HPTN Team

The Botswana Harvard AIDS Institute Partnership (BHP) has gone through a successful European Medicines Agency (EMA) inspection for the [HPTN 084](#) Study, “A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir

Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women.” The study is being conducted in 20 clinical research sites in seven sub-Saharan Africa. The inspection was conducted from 27th – 31st March 2023 by EMA representative

inspectors from the Italian Medicines Agency in Italy and one from INFARMED, I.P. from Portugal. Botswana Medicines Regulatory Authority (BoMRA), which is the drug regulatory agency in Botswana were invited by the EMA as observers.

The EMA is an agency of the European Union (EU) in charge of the evaluation, supervision and regulation of pharmaceutical products licensed for use within the EU. The inspection was undertaken at two selected study research sites; Emavundleni in South Africa and BHP Gaborone. The sponsor of the clinical trial the Division of AIDS (DAIDS) at the National Institutes of Health (NIH), United States of America Government (USG) was also included in the process.

The EMA inspection was to assess Good Clinical Practice (GCP) during the conduct of the trial consistent with international ethical and scientific quality standard for designing and reporting clinical trials that involve the participation of human subjects. The five-day long GCP inspection was held at the request of the Committee for Medicinal Products for Human Use (CHMP) on the conduct of the HPTN 084 clinical trial in accordance with regulation procedures and policies, mandated as part of licensure application for Long Acting Cabotegravir use within the EU.

The inspection was also meant to verify efficacy and safety data reported in the marketing authorisation application by the drug manufacturer. In addition, to verify the compliance with GCP, the inspection also assessed all applicable study conduct requirements like adherence to protocol, proper clinical records, obtaining of informed consent, reporting of adverse events and study drug accountability.

This was BHP's first EMA inspection and the organisation is proud of the positive findings. BHP Regulatory Coordinator, Tumulano Sekoto says the overall positive results of the inspection authenticates robustness, validity and integrity of the data, while testifying to the high-quality standard and ethical conduct of the study by BHP.

"Compliance with GCP standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical trial data are credible. So, the positive findings are testament of ethical conduct of quality research by BHP," said Sekoto.

"The success of this EMA inspection affirms the quality of research that is conducted within the BHP and is testimony to the scientists, research staff and all individuals affiliated with the institution. Indeed, this successful inspection would not have been possible without their invaluable contributions to the overall mandate of the BHP," said Dr Joseph Makhema, local Principal Investigator for the HPTN 084 study.

The inspection concluded that the study has been conducted at an acceptable level of compliance with GCP and internationally accepted ethical standards.

For study results, read [The Lancet, Volume 399, Issue 10337, P1779-1789, May 07, 2022.](#)



BHP Scientists Present Abstracts at International Conferences



Natasha Onalenna
Moraka



Boitumelo Zuze



Doreen Ditshwanelo



Maureen Sakoi-
Mosetlhi



Modiegi Diseko

Botswana Harvard AIDS Institute Partnership (BHP) continues to generate scientific data that is critical for public health policy and programming locally and globally, through collaborative research. International scientific conferences represent an opportunity to not only share data from Botswana but also to learn from others whilst continuing to build local research capacity critical to advance the country's "Vision 2036" agenda towards a knowledge-based economy. BHP's contribution to the knowledge-based economy involves generating data that contribute to improving health outcomes and preserving lives.

So far this year, four BHP scientists (including a Study Nurse Coordinator) presented their abstracts at the Conference on Retroviruses and Opportunistic Infections (CROI) on February 19-22, 2023, in Seattle, Washington State, to share and expose their research to international peer review. This also offered opportunity to network with experts in different public health areas.

CROI was established in 1993 as a forum for basic scientists and clinical investigators to share research about the epidemiology and biology of human retroviruses, most notably HIV. Three Laboratory Scientists, Natasha Moraka, Boitumelo Zuze and Doreen

Ditshwanelo and Maureen Sakoi-Mosetlhi, Tatelo Study Coordinator presented their abstracts at this year's conference.

Natasha Moraka presented an abstract titled, "[*High Predicted bNAb Resistance Among Adults with HIV-1 Seroconversion in Botswana.*](#)" She reported low levels of antiretroviral (ART) drug resistance mutations (SDRMs) but a high prevalence of predicted broad neutralizing antibody (bNAb) resistance in adults with HIV seroconversion in Botswana. Moraka's research sought to determine HIV ART drug resistance mutations and predict resistance to 33 known bNAbs using proviral HIV-1C sequences from adults with documented HIV-1 seroconversion in Botswana.

Boitumelo Zuze's abstract was titled "[*Fostemsavir Resistance-Associated Mutations in HIV-1C strains from Botswana.*](#)" Her study aimed to investigate the prevalence of fostemsavir-associated resistance (FTR) mutations among ART-naïve and-experienced individuals with virologic failure in the HIV-1 subtype C epidemic in Botswana. The study found that the overall prevalence of FTR drug resistance mutations was similar in both ART-naïve and ART-experienced individuals with virologic failure in a setting with no prior FTR exposure.

Doreen Ditshwanelo's poster was on the [Evolutionary History of Hepatitis B Virus Sub-Genotype D3 in Botswana](#). This study was conducted to describe the origins, introduction, diversity and evolutionary patterns of HBV sub-genotype D3 circulating in Botswana. It is the first study to give insights of HBV/D3 evolutionary dynamics in Botswana aiding in theoretical HBV management and disease tracking.

Moraka, Zuze and Ditshwanelo are BHP fellows at the BHP Laboratory. Moraka was awarded an International Investigator Scholarship while Zuze and Ditshwanelo were awarded New Investigator Scholarships to give poster presentations at CROI 2023 and they were accompanied by their supervisors, Drs Sikhulile Moyo and Simani Gaseitsiwe.

Maureen Sakoi-Mosetlhi used [Tatelo](#) data "a study on treatment with bNabs in children with HIV in Botswana" for a poster titled "[Caregivers of Children with HIV in Botswana Preferred Monthly IV bNABs to Daily Oral ART](#)". Sakoi-Mosetlhi evaluated caregivers' perspectives of the use of the two bNABs (VRC01LS and 10-1074) that children received through the Tatelo study. Study findings show that monthly intravenous bNab infusions were highly acceptable to caregivers of children with HIV in Botswana and it is preferred over standard ART by most. Therefore, caregiver acceptability is an unlikely barrier to bNab uptake and eventual programmatic use for children living with HIV.

Meanwhile, Study Coordinator Modiegi Diseko for [Tsepamo Study](#), "a birth outcomes surveillance study among infants born to HIV-infected women and exposed to different ART versus HIV-uninfected women in Botswana" presented an oral abstract on Neutral Tube Defects Surveillance in Botswana at the International Conference on Birth Defects and Disabilities in the Developing World ([ICBD](#)) in Santiago, Chile on the 2nd of March 2023.

Natasha Onalenna Moraka was also one of the 32 early career investigators (ECIs) worldwide and the only one from Botswana who received a Bill & Melinda Gates scholarship to attend the 2023 Collaboration for AIDS Vaccine Discovery ([CAVD](#)) Africa Regional Meeting held in February 13-16 2023 at The Westin Hotel in Cape Town. Moraka presented her abstract titled "[High Predicted bNABs Resistance but Low-Level HIV Drug Resistance Among Adults With HIV-1 Seroconversion in Botswana](#)" in honour and as part of the Norman L. Letvin Early Career Investigator Presentations. Her supervisor, Dr Simani Gaseitsiwe also attended the meeting.



Doreen Ditshwanelo (Left) presenting a poster at CROI



Natasha Onalenna Moraka (Left) at the Collaboration for AIDS Vaccine Discovery (CAVD) Conference

Dr Koofhethile leads BHP's HIV Cure related research



Dr Catherine K. Koofhethile

Dr Catherine Kegakilwe Koofhethile, a research scientist at Botswana Harvard AIDS Institute Partnership (BHP) is pursuing a complex research study which aims to advance human immunodeficiency virus (HIV) cure. Dr Koofhethile has been studying HIV reservoir mechanisms of HIV persistence in infants and adolescents and is the principal investigator for the Phodiso Study that seeks to understand the HIV-infected immune cells that remain latently infected in the body despite successful antiretroviral therapy (ART).

These viral reservoir cells, Dr Koofhethile explains that they can be reactivated if treatment is interrupted and this reality makes HIV to remain a concerning global epidemic. The study therefore seeks to study children and adolescents living with HIV in Botswana who started taking ART within the first year of life and have been on long-term ART and virally suppressed for nearly two decades.

"I am trying to understand the mechanisms of HIV persistence in People living with HIV who are undergoing long-term Antiretroviral treatment. Basically, I want to know why HIV still sticks around even when someone is on successful ART and has no detectable viral load," explains Dr Koofhethile.

The Principal Investigator describes the reservoir as a collection of latently infected cells which contain potentially infectious virus that may be transcriptionally silent (meaning it is sleeping) and therefore the immune

system is not able to recognize these infected cells and kill them.

"The reservoir is the biggest obstacle to finding a cure for HIV," asserts the Investigator. She says these latently infected cells can remain suppressed for a long time, and if one stops treatment, they can get activated and start producing the virus again consequently making the viral load to be detectable again.

"When we study the HIV reservoir, we look for the frequency of intact proviruses, meaning viruses that are potentially infectious. If these are present, we want to know where they insert themselves into the human genome. When HIV infects cells, particularly CD4 T cells, it becomes part of the human genome. So, it is important for us to also determine where the virus is integrating, because there are two possibilities: HIV can integrate into active genes which can allow viral rebound to occur should we stop ART, or HIV can integrate into non-active genes. In the second scenario, we do not expect viral rebound to occur in the absence of ART" Dr Koofhethile elaborates.

"I want to know why HIV still sticks around even in the presence of successful treatment. If we can master this, maybe we might be able to advance the field and contribute towards the development of ideas or strategies to eliminate HIV," she said.

Dr Seatla awarded APTI Postdoctoral Fellowship



Dr. Kaelo K. Seatla

Dr Kaelo Seatla, a Research Associate at the Botswana Harvard AIDS Institute Partnership (BHP) has recently been awarded a highly competitive and prestigious four-year Postdoctoral Training Fellowship supported by the U.S. National Institutes of Health (NIH), [African Academy of Sciences](#) (AAS) and Bill & Melinda Gates Foundation (BMGF) called the African Postdoctoral Training Initiative (APTI).

The APTI programme entails placement/training at various laboratories of the NIH Institutes or Centers for two years before Fellows return to their home institution in Africa for another two years of program support. The Bill & Melinda Gates Foundation's support to the postdoctoral fellows includes seed funding for their research upon their returning to their home institution.

Dr Seatla is among the 10 outstanding early career scientists from nine African countries who have been awarded fellowships to build their capacity to conduct cutting-edge research in global health. The 10 fellows were competitively selected from 296 applicants.

The third cohort of the [APTI Fellows \(APTI 3\)](#) comprises of five women and five men and they will assume their positions in NIH host laboratories in October 2023. Their research activities shall focus on specific global health research priority areas including human immunobiology, microbiome research, drug discovery, genomics, HIV, malaria, maternal, neonatal and child health.

Dr Kaelo Seatla trained in clinical research at BHP and completed his PhD with a focus in virology at the University of Botswana. He is an active clinician, with focus on treating patients with highly drug-resistant HIV.

He is a recipient of prestigious awards that include, 1) Africa Research Excellence Fund Research Development Fellowship, 2) Harvard University, Boston University, Northwestern University, and University of New Mexico (HBNU) Fogarty Global Health Fellow, 3) Harvard University Center for AIDS Research Developmental Award, and 4) PhD fellowship by the Sub-Saharan African Network for TB and HIV Research Excellence ([SANTHE](#)).

Dr Seatla's primary research interests are in the development and implementation of low-cost HIV drug resistance testing assays, monitoring for drug resistance among people with HIV who are taking contemporary antiretroviral treatment regimens, and evaluating in-vitro antiretroviral susceptibility of HIV-1 subtype C viruses that harbour drug resistance mutations (including the correlation between genotypic, viral replication capacity, and phenotypic profiles of HIV-1 subtype-C with extensive drug resistance mutations, including to integrase strand inhibitors).

Dr Seatla aims to continue to develop research skills in studying genotypic (including with next generation sequencing) and phenotypic drug resistance and spread of HIV, and applying these skills to emerging/re-emerging pathogens in Botswana.

He is committed to a collaborative career in translational research that uses both his clinical and laboratory skills, and hopes to mentor future early-stage investigators in Botswana and the region.

BHP integrates community voices in its studies



CAB Members in a Meeting

Botswana Harvard AIDS Institute Partnership (BHP) values the involvement of community members in the conduct of its clinical trials. The institute has a Community Advisory Board (CAB) that plays an important role of helping researchers to better understand the communities in which they are conducting clinical trials, ensuring that the community is involved in the development and conduct of the research. Investigators meet with CAB members from time to time to update them on study progress and also to get feedback from the community's perspective.

On May 13, 2023, BHP investigators met with the CAB at the Clinical Trials Unit (CTU) Boardroom for study updates and for the review of some study protocols that are still in development (CAB drafts) as a way of integrating community perspectives into the research studies conducted at BHP and globally. This is meant to ensure that studies address the needs of communities and processes are tolerable, acceptable and do not outweigh benefits (study equipoise). CAB drafts are usually from Clinical Trials Network studies (AIDS Clinical Trials Group Network ([ACTG](#)), HIV Prevention Trials Network ([HPTN](#)) and International Maternal Pediatric Adolescent AIDS Clinical Trials Network ([IMPAACT](#)).

The review of the protocols and other study related documents such as informed consent forms and recruitment materials by CAB members ensure

understanding of the study design process and execution so that they can present the studies better to their communities for buy in. The CAB is comprised of volunteers from various organisations, youth groups, community members and government departments. CAB members help to interphase BHP with communities and organisations they represent.

They also represent BHP in various community structures in various Clinical Trials Network. Three members of the BHP CAB represent BHP on the ACTG's Community Scientific Sub-Committee (CSS), two on the IMPAACT Leadership Group, two on the HPTN Community Working Group and one on DAIDS' HIV AIDS Network Coordination (HANC). The BHP CAB helps build mutually beneficial relationships between the researchers and the communities in which the clinical trials are being implemented.

During the meeting, the board heard updates for the Network studies conducted at BHP as well as the Inter Care study which seeks to integrate hypertension care into HIV care in various communities across Botswana. Some intervention communities will have intervention of training of health care providers and adherence partners (mopati) in delivery of hypertension management care, while others will continue with standard of care and will be used as control.

New Employees



Dr. Rachita Suresh

Dr Rachita joined the Botswana National Meningitis Survey Study as a Study Physician, on 3rd April 2023



Keadiretse Motlhabi

Ms. Keadiretse joined the BHP DMC Team as Systems Developer/Analyst II on the 3rd April 2023.



Merlin Alvina Bafana

Ms. Merlin was appointment as a Regulatory Administration Officer on 1st April 2023.



Caroline Mazongo

Ms. Caroline joined Tsepamo Study on 1st May 2023, as a Research Assistant



Keamogetse Matlholo

Ms. Keamogetse joined the BHP Lab Department as a Lab Technician Intern on 24th April 2023.



Chobbie Moagi

Mr. Chobbie joined Botswana Harvard Partnership on 5th May 2023 as Security Guard.



Cecilia Ratshukudu

Ms. Cecilia joined Botswana Harvard Partnership on 5th May 2023 as a Security Guard.



Marea Neo Pema

Ms. Neo joined the Lab Team Bioinformatician as an Intern on 1st January 2023.



Dr. Marcella Yoseph

Dr. Marcella joined BHP on the 2nd May as a Study Coordinator, for Tshireletso Study.

Promotions



Ame Diphoko

Ms Diphoko's has been promoted to the position of Senior Systems Analyst/ Developer effective 1st April 2023. Her career with BHP commenced in August 2018 as an Intern and she was later promoted to Assistant Systems Analyst/ Developer in August 2019.



Sharon Motlhale

Sharon joined BHP on the 1st September 2022 under Tshireletso Study as a Research Nurse and she has been promoted to Head Research Nurse on the 1st April 2023.

Finance Organisational Development

The Finance and Grants Department has been reviewing its financial operations to ensure effectiveness and efficiency. After careful consideration and analysis, Management decided to re-design the department to better align with BHP goals and priorities. This Organisational Re-design has come with a number of changes, including the creation of new roles.

One of the primary goals of this Re-design is to streamline financial processes and improve the Finance and Grants Department's ability to deliver timely and

accurate financial information. The new roles were created to support our Strategic Initiatives, and they will also provide more in-depth analysis of Grants data and help make more informed decisions with BHP Finances.

Congratulations to all promoted staff members! We wish them success in their new roles and we are very confident that they will meet the new responsibilities that accompany their new positions with the same level of enthusiasm and enterprise they have exhibited since working for BHP.



Cornelius Gaetsaloe

Mr. Cornelius Gaetsaloe has been promoted to Chief Operations Officer.



Dineo Thebe

Ms. Dineo Thebe has been promoted to Director of Finance and Grants



Ronald Ruele

Mr. Ronald Ruele has been promoted to Finance Manager



Kevin Opelkgale

Mr. Kevin Opelkgale has been promoted to Grants Manager



Winnie Motlhagodi

Ms. Winnie Motlhagodi has been promoted to Senior Accountant



Akanyang Motlhanka

Ms. Akanyang Motlhaka has been promoted to Senior Grants Officer

Policy Corner

GRIEVANCE PROCEDURE

A grievance procedure is a means of internal dispute resolution by which an employee may have his or her grievances addressed. The BHP grievance procedure supports and encourages employees to raise concerns without fear of any negative repercussions. It encourages openness and aims to foster an environment of dealing with complaints fairly and timely

The Grievance Policy Procedure

The Grievance Policy Procedure can be found in Section 19 of the BHP Conditions of Service

Stage 1:

Any Employee who wishes to raise a question in which he/she is directly involved should, in the first instance, raise the issue with the immediate Program Manager or Coordinator in writing setting out the nature of the complaint and the desired settlement. They shall meet and try to settle it within five working days.

Stage 2:

If not resolved during Stage 1, the Employee may raise the issue in writing within two weeks with the COO and they shall meet and attempt to settle it within a further period of up to five working days. A brief record of the grievance, the agreement/decision and the action taken shall be made by the COO and placed in the employee's personnel file. A copy shall be given to the Employee concerned.

Stage 3:

If the grievance has not been resolved by the COO, the Employee may refer the matter, in writing, to the Project Director/CEO. The Project Director/CEO shall arrange a meeting, normally within five working days of notification, to discuss the grievance and attempt to resolve the matter. A brief record on the grievance, the agreement/decision and the action taken shall be made and kept on file. A copy shall be given to the Employee. This is the final stage of the procedure. In the event any of the said people to report the grievance are not available, the acting supervisor in place will stand in for them.

Prohibition of Retaliation by Program Director, Manager or Coordinator No Employee (Director, Manager or Coordinator) shall retaliate against a complainant. Any attempts to penalise an employee for initiating a complaint/grievance through any form of retaliation shall be treated as a separate allegation of discrimination. Frivolous or malicious complaints by Employees In the event that a claim is found frivolous, appropriate Partnership sanctions shall be taken against the complainant, including disciplinary action where appropriate.

Management commits to settling all grievances fairly, promptly and as near as possible to the point of origin.



Meet And Greet Sessions

Following the appointment of Dr Gaerolwe Masheto as the new Deputy CEO of BHP in March 2023, Human Resources Department organised “meet and greet sessions” from the month of May to June 2023 to introduce him to the entire BHP staff. The sessions also provided an opportunity for Executive Management to engage with staff on various needs critical for high performance and work satisfaction. It also provided an opportunity for management to assess the work environment and team morale and commitment.

Overall, the feedback received from employees was positive and constructive. They expressed a genuine interest in their work and a desire to contribute to the success of the organization. However, there were some areas where employees identified opportunities for

improvement.

Employees expressed a desire for more opportunities for professional development, urging management to consider introducing a robust training and developmental plan that fosters career progression. They advised that individual study budgets should also include soft skills training and that BHP should also have Training Grants for Support Services.

Staff members pleaded with management to improve Annual Contract Renewal Adjustments (Inflation Adjustments) as well as overall employee benefits (annuity funds and financial trainings). They also asked management to introduce long term contracts for job security.



BHP Francistown team



BSRHI team

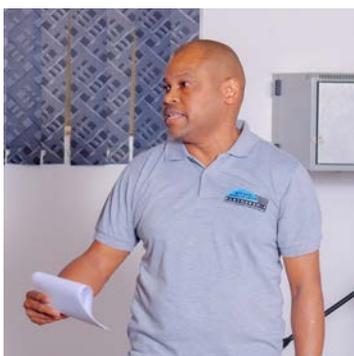
Office Of Strategy Management

The Office of Strategy Management hosted a Strategy Review session on the 26th and 27th April 2023 to assess BHP's current state and plan for the future. The invitation was extended to all Study Coordinators, Managers and Middle Management, with an attendance of about 30 Employees.

The objectives of the reviews sessions were met, the team was able to identify key areas of focus and develop a roadmap that aligns with BHP goals. The level

of engagement and collaboration that was displayed throughout the session was impressive. It was clear that everyone was committed to working towards a shared vision and working together to achieve BHP goals.

This year marks the final year of the current BHP Strategy and the main areas of focus are to re-align the BHP's Strategic Measures and improve Strategic Reporting tools.



VISION

To Be a World-Renowned Public Health Institute.

MISSION

To Fight HIV/AIDS and Emerging Public Health Challenges Through Innovative Research, Education, and Capacity Building That Impacts Policy and Practice.

CORE VALUES

BENEFICENCE

INNOVATION

COLLABORATION

EXCELLENCE

BOTHO

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