In April 2015 the Institute of Human Virology of the University of Maryland School of Medicine was the recipient of a grant from the President’s Emergency Plan for AIDS Relief (PEPFAR) to provide capacity building through training and mentoring for care and treatment of people living with HIV (PLHIV) in Botswana. Subsequent to this award, the Botswana-University of Maryland School of Medicine Health Initiative (BUMMHI) was created as the local implementing partner for this PEPFAR grant. Since its inception BUMMHI has been providing training and support for treatment of PLHIV at over 70 clinical sites throughout the country.

Botswana has suffered greatly from the HIV epidemic and is a country with the third highest prevalence of HIV infection in the world, at 18.4%. Prior to this year, HIV-infected individuals with CD4 counts less than 350 cells/ul or with opportunistic infection were initiated on antiretroviral treatment with a drug regimen containing efavirenz, a non-nucleoside reverse transcriptase inhibitor. In early 2016 Botswana updated its national HIV treatment guidelines and started implementing “Treat All”, in which all HIV-infected persons are initiated on antiretroviral therapy regardless of CD4 count or World Health Organization (WHO) clinical stage. First-line antiretroviral therapy has also been changed from efavirenz-based to an integrase inhibitor-based regimen containing dolutegravir. Thus, beginning this year all newly diagnosed HIV-positive individuals are initiated on a dolutegravir-based regimen, regardless of immunological clinical stage.

Dolutegravir is a relatively new antiretroviral drug that holds great promise for maintaining durable viral suppression with minimal drug toxicity in HIV-infected persons. Premarketing clinical trials have demonstrated that dolutegravir is as equal or superior to other available antiretroviral therapy. Since dolutegravir has only recently been introduced on the market, though, there is a paucity of data on its
use in routine clinical practice—especially in sub-Saharan Africa. The purpose of this project is to
determine the effect of the universal rollout of a dolutegravir-containing regimen in Botswana on rates
of HIV treatment failure, drug toxicities, and other adverse events at two major referral centers. Two
students from the University of Maryland, Baltimore will stay in Botswana for three weeks during the
summer of 2017 and will work closely with myself as well as with our clinical teams of physicians,
nurses, pharmacists, and laboratory and quality improvement specialists. They will conduct this study at
two outpatient HIV treatment centers supported by BUMMHI—one of which is in Princess Marina
Hospital, the national referral hospital in Gaborone, and the other at Nyangabgwe Referral Hospital in
Francistown. At these two sites, students will review clinic records of all HIV-positive individuals who are
currently being treated at these two clinics with dolutegravir-based antiretroviral therapy. They will
collect data on rates of viral suppression as well as drug-related adverse events and toxicities. Rates of
viral suppression on dolutegravir-based antiretroviral therapy will be compared with local historical data
for viral suppression on antiretroviral drug regimens not containing dolutegravir. Given the available
literature on the efficacy of dolutegravir, we anticipate that rates of virologic failure and drug-related
adverse events will be significantly lower with dolutegravir-based regimens than with the previously
used antiretroviral regimens.

We plan to present an abstract of our study findings at local and international conferences and to
publish the same in a scientific journal. Our University of Maryland students will assist in the preparation
of these presentations, abstracts, and manuscripts. While working in Botswana, students will attend all
meetings between the clinical teams and representatives of the Botswana Ministry of Health as they
arise.

Pre-departure: In the several months prior to arriving in Botswana, students will receive an overview on
Botswana as well as the current HIV epidemic in the region. Dr. Saleeb will orient students to BUMMHI,
planned activities, and their living experience in Botswana. Dr. Saleeb works in Botswana full time but
will be traveling to Baltimore and holding two (2) required sessions in December 2016 and again from
mid-March to mid-April 2017. Students will also be required to attend two CGEI orientation sessions.