SEMIANNUAL RESEARCH REPORT

January – June 2022

Acknowledgments

The AMPATH Kenya Research Program Office is grateful to our sponsors and research partners who contribute to the success of our research program. Thank you to everyone who contributed to this report and our efforts to improve the health of people in Kenya and other resource-limited settings around the world.

Editorial Team

Jepchirchir Kiplagat-Kirui
Michael Scanlon
Whitney Turientine
Kara Wools-Kaloustian
Winstone Nyandiko

Contacts	
Jepchirchir Kiplagat-Kirui Associate Director AMPATH Kenya Research Program AMPATH Centre P.O. Box 4606 Eldoret, Kenya Email: research.manager@iukenya.org Phone: +254 53 203 3471 Fax: +254 53 206 1992	**Whitney Turientine** Program Manager AMPATH Kenya Research Program Indiana University Center for Global Health 702 Rotary Circle, RO131 Indianapolis, IN 46202 Email: research.manager@iukenya.org Phone: +1-317-274-4189 Fax: +1-317-274-9124
Please visit the AMPATH Research Program website to learn how our research programs are helping improve the health of people in Kenya and around the world. *https://www.ampathkenya.org/research*	

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Research Program Vision, Mission & Values

Vision

We envision a vibrant, world-class, Kenyan-led community of researchers engaged in the continuous improvement of health globally.

Mission

Guided by the principle of leading with care, we work in partnership to develop local research talent and to identify, develop and disseminate relevant and timely information to improve the health of people in underserved populations.

Values

In our work, we embrace:

- Service with humility
- A spirit of collaboration and partnership
- Integrity in relationships
- Mutual respect and mutual benefit in organizational partnerships
- Efforts to eliminate health disparities
- A sustainable infrastructure for research

Strategic Priorities

After internal and external stakeholder surveys and interviews, the AMPATH Kenya Research Program Office (RPO) convened a two-day strategic planning meeting in September 2019 in Eldoret, Kenya. The meeting included more than 40 key research program leaders and stakeholders tasked with reviewing and evaluating the program's strategic priorities and developing a new strategic plan for the next three years. The following strategic priorities were identified:

1. Strengthen development of a **well-resourced and sustainable infrastructure for research** that enables the efficient conduct of high-quality research.
2. Increase the number of **successful independent investigators** working in collaborative, interdisciplinary research teams by providing better access to high-quality training and mentorship.
3. Enhance **supportive, research-intensive cultures** within the schools and departments of all AMPATH partners.
4. **Accelerate growth in relevant, high-yield research initiatives** that will improve policy and strengthen the health systems and communities we serve including biomedical innovations, health economics/equity, population health, informatics, and implementation science research.
5. Incorporate research into ongoing efforts to **expand AMPATH innovations to additional underserved populations beyond Kenya.**

Based on these strategic priorities, the RPO created a 2020-2023 work plan with input from key stakeholders and leadership to implement the program's new strategic plan. The work plan was included in the AMPATH Kenya Research Semi-Annual Report July – December 2021.

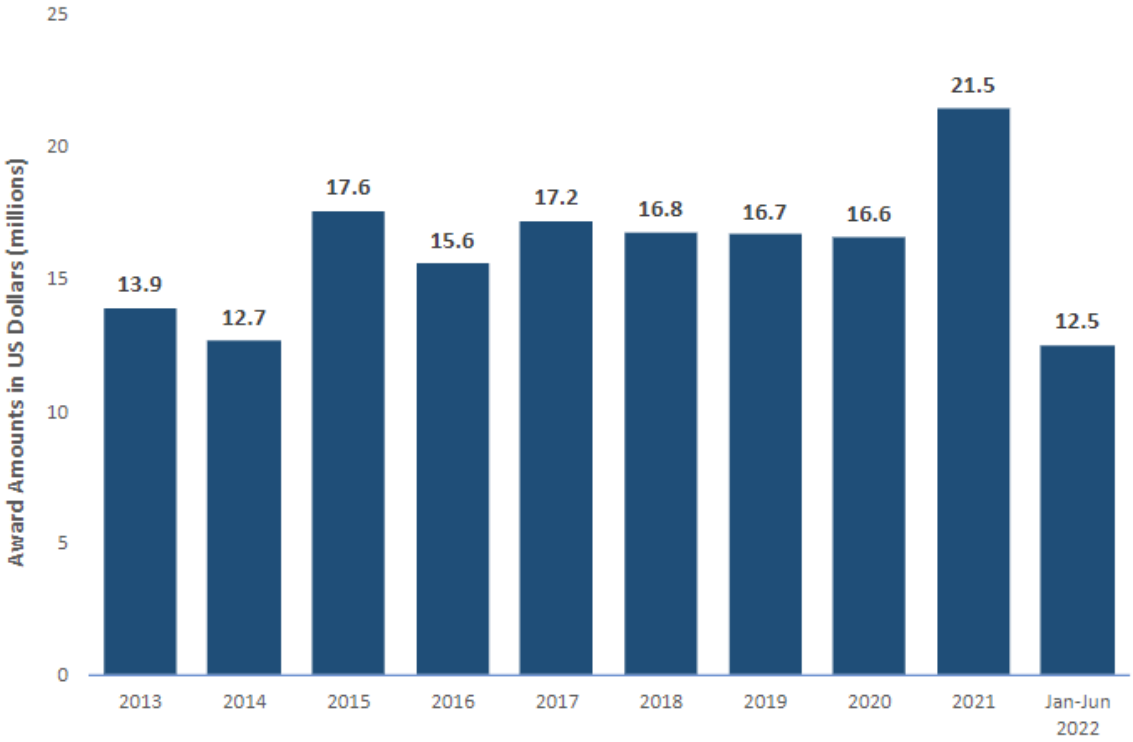
The AMPATH Research Program is transitioning from a 3-year to 5-year strategic planning cycle starting in 2023. In 2023, the AMPATH RPO will conduct internal and external stakeholder surveys and interviews and plan to convene an in-person strategic planning meeting in January of 2024 to inform the 2024-2029 work plan.

Grants

January – June 2022 Award Metrics At-a-Glance

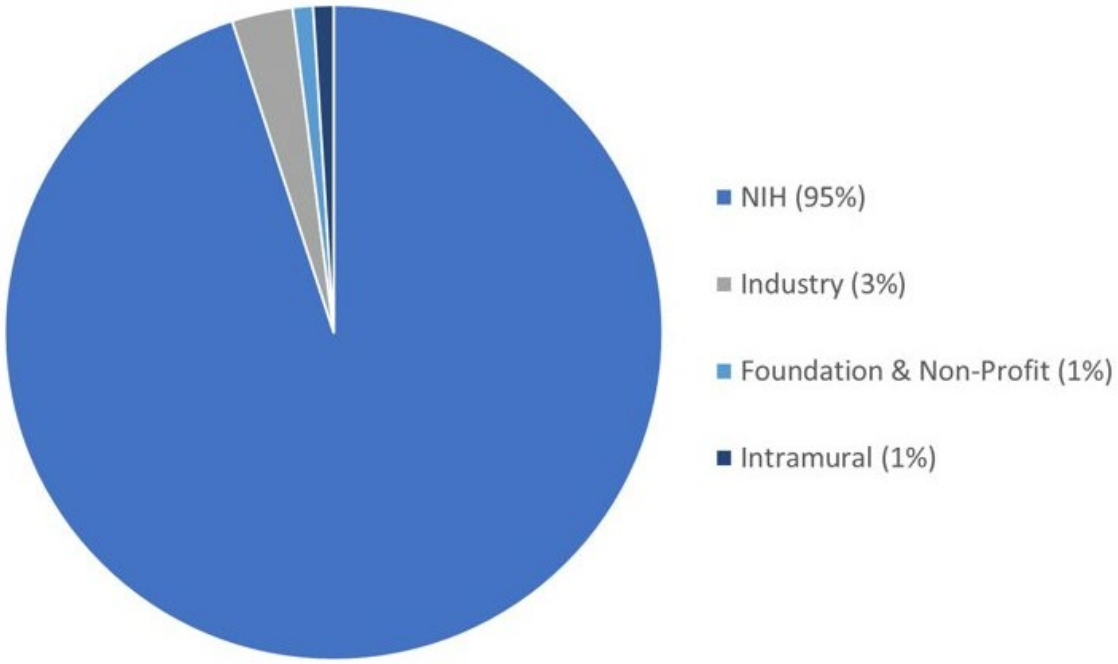
In the first half of the 2022 calendar year, AMPATH-affiliated investigators received a total of US $12.6 million in awards for research and training activities, including US $3.4 million in funding for new research projects and US $9.2 million in funding for continuing research projects, which is on track for another record-breaking year of research funding at AMPATH (Figure 1). This increases AMPATH's cumulative total of research and training awards to approximately US$ 222.5 million.

Figure 1. Ten-Year Trend in Total Awards, 2013 – 2022



Consistent with previous years, NIH funding remained strong in the first half of 2022, representing 95% of the total funding received, while funding from industry sponsors, foundations/non-profits and intramural awards made up the remaining 5% (see Figure 2).

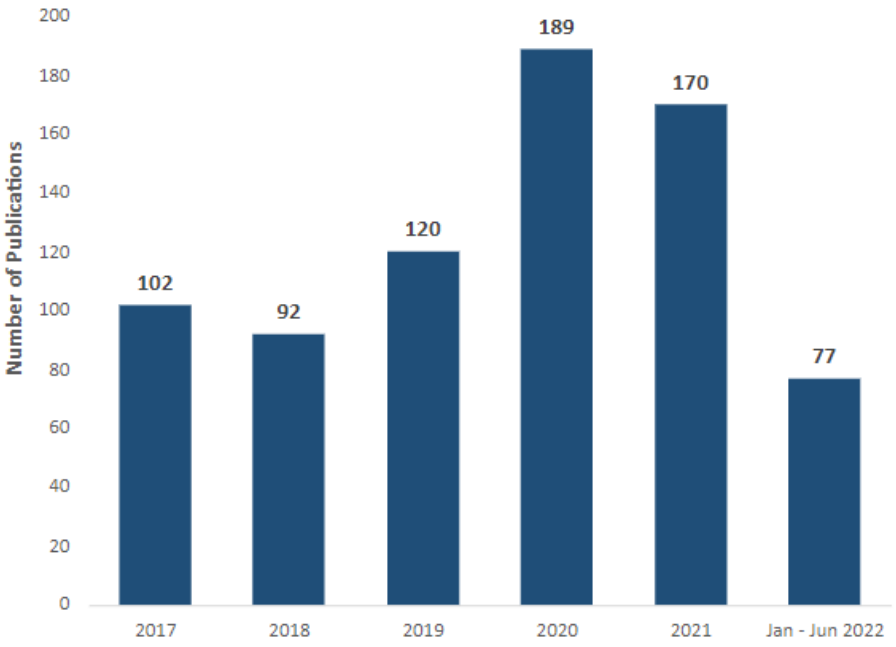
Figure 2. Research Funding Received by Sponsor Type, January – June 2022



Publications

Investigators from Moi University, Moi Teaching and Referral Hospital (MTRH), and AMPATH Consortium institutions published 77 articles in the reporting period (see Figure 3). HIV-related research publications remained strong in the first half of 2022 (17 publications) with a diverse array of research including: adherence, disclosure and stigma, clinical trials of treatment regimens, HIV drug resistance, HIV-related co-morbidities, and research ethics. AMPATH investigators also published widely in the areas of cancer (9), non-communicable diseases (8), substance use and mental health (8), COVID-19 (6) and other areas. AMPATH researchers contributed to several publications from regional and/or global studies through several research networks and collaborations. See Appendix 1 for a full list of publications by AMPATH affiliated investigators during the reporting period.

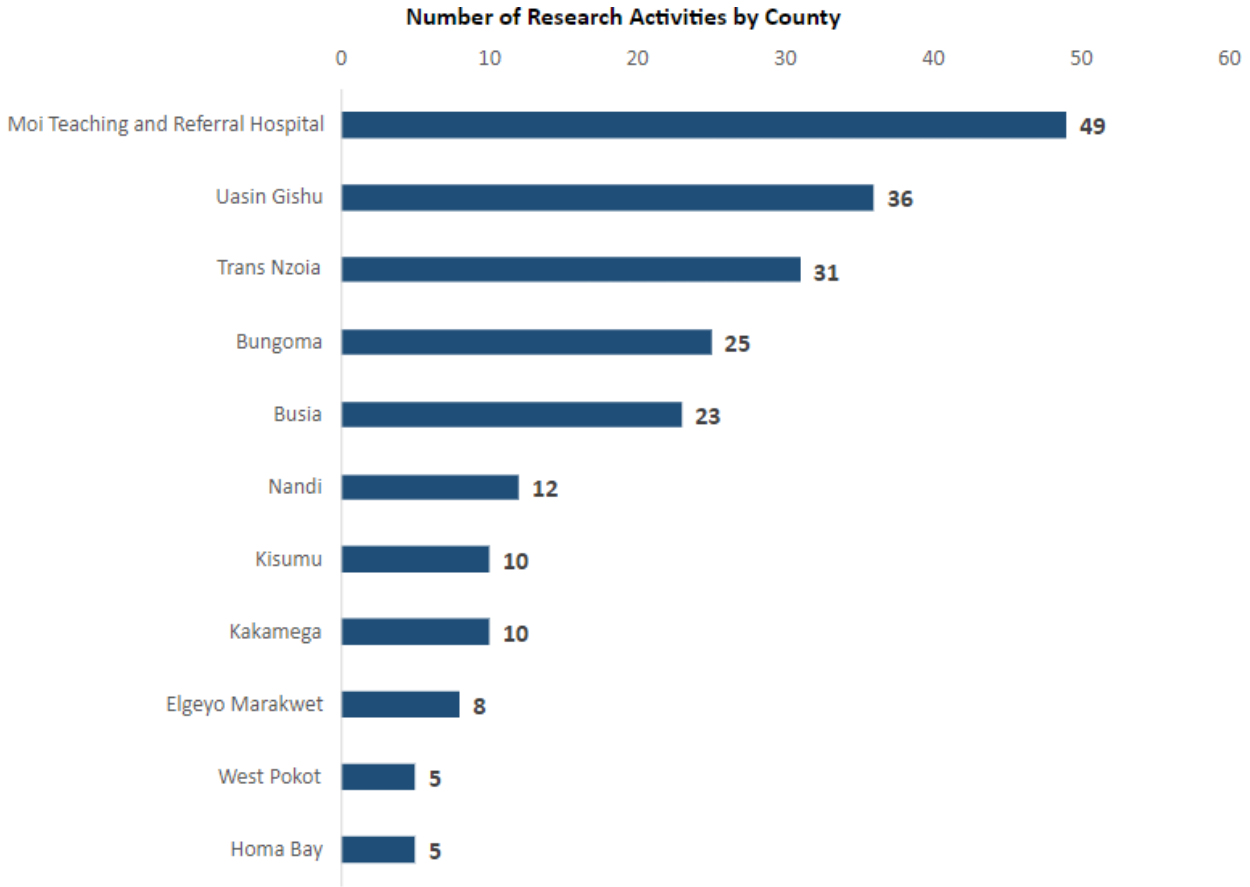
Figure 3. Articles Published by AMPATH Investigators, 2017 – 2022



Geographic Reach of AMPATH Research Activities

A total of 78 research projects at AMPATH completed requests for information related to new, ongoing or recently completed studies during the reporting period of January-June, 2022. As shown in Figure 4, while Uasin Gishu County (home to Eldoret and MTRH) is the most common location for research activities, AMPATH researchers are engaged in research activities across western Kenya. AMPATH investigators are part of regional and global research and training activities through a number of projects and consortia funded by the NIH and other major funders. Some of these large scale projects and consortia include the NIH-funded Global Network for Women's and Children's Health Research, IeDEA Consortium, and Global Health Program for Fellows and Scholars, and clinical trials at the Moi University Clinical Research Centre through the AIDS Clinical Trials Unit (ACTG) and European and Developing Countries Clinical Trials Partnership, among others.

Figure 4. Research Projects by County* in Kenya



**Several projects take place in more than one county. Projects reported all counties where research activities were taking place. Research projects taking place at Moi Teaching and Referral Hospital (MTRH), which is located in Uasin Gishu County, are listed separately. Additionally, other counties with at least one research project include: Bomet, Kericho, Kisii, Migori, Nakuru, Siaya, Turkana and Vihiga.*

Other Activities & Achievements

In the first half of 2022, the AMPATH Kenya Research Program made progress in several key areas in line with the strategic plan:

AMPATH Research Launches Re-Structured AMPATH Facility Fee - The AMPATH Facility Fee was redesigned to simplify the fee structure for investigators at AMPATH and move the administration of the fee from the IU Center for Global Health to Research and Sponsored Projects Office (RSPO) in Kenya. A new fee structure was approved by the AMPATH Executive Committee in early 2022 and fully implemented July 1, 2022. The fee continues to provide critical support to research infrastructure and resources in Kenya so that AMPATH remains a global leader in innovative and impactful research.

Finalized a Mentorship Short Course for Junior Investigators – A curriculum for academic mentorship was developed by the AMPATH Kenya Research Program in collaboration with faculty leadership at Moi University and Eider Africa, a firm in Nairobi that specializes in academic research mentorship program development. The curriculum was translated to an online learning platform, Canvas, and will be pilot tested by senior Moi faculty at the College of Health Sciences later in 2022.

Supporting Professional Development for Junior Faculty and Staff – A professional development series was launched by the AMPATH Kenya Research Program that targets junior faculty and researchers and research staff for development in various research skills and areas. In 2022, sessions have been organized on conducting literature reviews, crafting an NIH biosketch, and scientific manuscript writing (led by Dr. Kara Wools-Kaloustian). AMPATH was also a host site for two University of Washington online global health courses – Monitoring and Evaluation in Global Health and Project Management in Global Health. Forty AMPATH research staff and junior faculty participated in each course.

Establishment of the Moi University Research Integrity Office – Moi University became the first university in Kenya to establish a Research Integrity Office under the Moi Directorate of Research. The Office was fully operationalized in April 2022 and oversees research integrity and misconduct policies and procedures across all schools, faculties and departments at Moi University. The establishment of the Research Integrity Office was supported in part by an NIH grant to Dr. Edwin Were and collaborators at Moi University and Indiana University.

Photo 1: Launch of the Moi University Research Integrity Office on April 25, 2022, at Moi University - Main Campus.

AMPATH Research Replication in Ghana, México and Nepal – In 2022, AMPATH launched new partnerships in Ghana, Mexico and Nepal based on the academic model for partnership developed in Kenya. The AMPATH Kenya Research Program leads an AMPATH research replication working group to identify, translate and adapt the lessons of the research program in Kenya and support new research and collaboration across AMPATH partners. Leaders from the University of Texas at Austin / AMPATH México visited Eldoret April 19-22 to meet AMPATH leadership and learn about the partnership. The Research Program Office coordinated visits with the co-director of research and representatives from Moi/MTRH Institutional Research and Ethics Committee, AMPATH Data Analysis Team, RSPO, among others.

Photo 2: The University of Texas at Austin team meets with leadership at the Moi University School of Public Health.

Photo 3: AMPATH leadership from Moi University meets with leaders from Icahn School of Medicine at Mount Sinai and Nepal's Dhulikhel Hospital.

Moi-NYU-Brown Data Science Launch – Leadership from two projects – the NYU-Moi Data Science for Social Determinants training program and Moi-Brown Partnership for HIV Biostatistics Training (NAMBARI) – hosted a Data Science Launch on April 26. The event served as an opportunity to bring together data science training programs to share plans and progress, as well as engage stakeholders across the programs, including faculty, current and past trainees, institutional leadership and the NIH.

Subscribe to the monthly AMPATH Research newsletter To stay updated on important activities at the AMPATH Research Program as well as new grant and funding opportunities, published articles from AMPATH investigators, and calendar events such as the AMPATH Works in Progress meetings. Contact the AMPATH Research Program Office (research.manager@iukenya.org) to subscribe.

Appendix – Bibliography and Study Reports

Appendix 1. Bibliography

The following bibliography includes AMPATH research publications published in the first half of 2022. Please contact the Research Program Office at research.manager@iukenya.org for a complete bibliography of AMPATH research publications published since 1989 along with full text articles.

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Appendix 2. Study Reports

The following study reports provide summaries of active AMPATH research projects at the end of the reporting period (June 30, 2022). Study reports and updates for 78 new, ongoing and recently completed studies were provided by the projects' principal investigator(s) or their designee and provide details on study team specific aims, sites, project period, sponsors, project status and publications. Summaries are organized alphabetically by study title and a linked index is listed below for easy navigation.

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Study Title	A cluster randomized trial of 'Teach HADITHI' teacher training intervention to reduce classroom HIV-related stigma in Kenya.
Principal Investigator(s)	Rachel Christine Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Edith Apondi (MTRH), Juddy Wachira (Moi University), Wanzhu Tu (Indiana University)
Study Type	Prospective intervention study
Specific Aim(s)	Aim 1: Assemble a multimedia teacher training curriculum package, focused on HIV and HIV stigma and adapted for maximum cultural relevance, curricular cohesion and impact among Kenyan primary and secondary school teachers. Aim 2: Assess the impact of the Teach HADITHI intervention on Kenyan teachers' attitudes, beliefs and knowledge about HIV and the level of HIV-related stigma among teachers. Aim 3: Examine whether HIV-infected children and adolescents in classrooms with teachers who have received the Teach HADITHI intervention report less perceived, enacted or internalized stigma compared to those in classrooms with teachers who have not. Aim 4: Examine the impact of HIV stigma training on stigmatizing knowledge, attitudes and beliefs about COVID-19.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	7/1/2018 - 4/30/2021
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction and follow-up. Research activities are limited to data analysis.

Study Title	A Phase 2, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Daily Bedtime TNX-102 SL in Participants with PTSD
Principal Investigator(s)	Lukoye Atwoli (Aga Khan University)
Collaborator(s)	Edith Kwobah (MTRH), Frank Njenga, Linet Ongeri, Sylvia Kemunto, Gabriel Kigen
Study Type	Double-blind randomized clinical trial.
Specific Aim(s)	Aim 1: To evaluate the efficacy of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in treatment of PTSD. Aim 2: To evaluate the safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in the treatment of PTSD.
Site(s)	Moi Teaching and Referral Hospital, KEMRI Nairobi, Aga Khan University
Project Period	7/1/2020 - 6/30/2023
Sponsor(s)	TONIX Pharmaceuticals
Status	Not started -- Study activities have not begun.

Study Title	A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 1
Principal Investigator(s)	Jeremiah Laktabai (Moi University)
Collaborator(s)	Diana Menya (Moi University), Wendy O'Meara (Duke University)
Study Type	Randomised controlled trial
Specific Aim(s)	The objective of this experiment is to identify the combination of RDT and conditional (diagnosis-dependent) ACT subsidies that maximize the percent of clients receiving an RDT. We will test two different RDT price levels and two discounted ACT price levels in a factorial design. ACT discounts are conditional on a positive RDT result. The primary outcome measure is the decision to purchase an RDT before purchasing a drug. Secondary outcome measures are: Decision to purchase an ACT stratified by testing status: (a.) Positive mRDT (b.) Negative mRDT (c.) No malaria test. All outcomes will be measured by interviewing the participant after they make their decision about whether to be tested and which medicines to purchase.
Site(s)	Bungoma, Trans Nzoia
Project Period	10/1/2018 - 9/30/2023
Sponsor(s)	NIH-NIAID

Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 2
Principal Investigator(s)	Jeremiah Laktabai (Moi University)
Collaborator(s)	Diana Menya (Moi University), Wendy O'Meara (Duke University)
Study Type	Randomised controlled trial
Specific Aim(s)	The objective of this study is to test the effect of provider-directed and patient-directed incentives on improving the management of suspected malaria fevers that receive care in the retail sector. Provider-directed incentives include small payments for taking the time to conduct malaria-RDT testing for participants with malaria-like illness. Patient-directed incentives are inexpensive RDT testing coupled with a conditional ACT discount. Outcomes will be measured by exit interviews on random days each month at each participating outlet. The primary outcome will be the proportion of all ACTs that are sold to individuals with a positive malaria diagnostic test. The major secondary outcome is the proportion of suspected malaria cases that are tested. This outcome will allow us to determine whether the conditional subsidy can drive demand for testing.
Site(s)	Bungoma, Trans Nzoia
Project Period	10/1/2018 - 9/30/2023
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	A5300B/I2003B/PHOENIx Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients (PHOENIx MDR-TB)
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	David Lagat (Moi University)
Study Type	Phase III, open-label, multicenter trial with a cluster-randomized superiority design
Specific Aim(s)	Aim 1: To compare the efficacy of 26 weeks of DLM versus 26 weeks of INH for preventing confirmed or probable active TB during 96 weeks of follow-up. Aim 2: To compare the safety (permanently

	stopping study drug due to treatment-related adverse events) of 26 weeks of DLM versus 26 weeks of INH for the treatment of presumed latent TB infection (LTBI) with MDR-TB.
Site(s)	Bungoma, Busia, Elgeyo Marakwet, Homa Bay, Kakamega, Kericho, Kisumu, Moi Teaching and Referral Hospital, Nakuru, Nandi, Siaya, Trans Nzoia, Uasin Gishu, Vihiga, West Pokot
Project Period	10/21/2020 - ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. No update provided for the current reporting period.

Study Title	A5381 Observational Cohort to Assess Therapeutic Efficacy and Emergence of HIV Drug Resistance Following Initiation of Tenofovir-Lamivudine-Dolutegravir (TLD) for First- or Second-Line ART or with Rifampicin-Containing TB Treatment
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	Fatuma Some (Moi University)
Study Type	Prospective cohort study
Specific Aim(s)	Aim 1: Among participants still on TLD at 6 months of follow up, to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations in each of the following groups: (a) Participants switching from first-line NNRTI-containing therapy with HIV-1 RNA >1000 copies/mL at start of TLD (Group 1a); (b) Participants switching from second-line PI-containing therapy with HIV-1 RNA >1000 copies/mL at start of TLD (Group 2a); (c) Participants switching from first-line NNRTI-containing therapy with HIV-1 RNA ≤1000 copies/mL at start of TLD (Group 1b); (d) Participants switching from second-line PI-containing therapy with HIV-1 RNA ≤1000 copies/mL at start of TLD (Group 2b); (e) Participants who are ART-naïve when starting TLD (Group 4). Aim 2: Among participants taking concomitant TLD (including an additional daily dose of DTG 50 mg) and RIF-containing TB treatment (Group 3), to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations at the end of concomitant treatment.
Site(s)	Busia, Elgeyo Marakwet, Homa Bay, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, West Pokot
Project Period	10/5/2020 - ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. No update provided for the current reporting period.

Study Title	Addressing bioethical research gaps in research with young people living with HIV (YPLWH) in Kenya
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai), Violet Naanyu (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Examine ethical issues in longitudinal clinical research with YPLWH in Kenya from the patient, caregiver, and other key informant perspective. Aim 2: Identify and analyze key bioethics guidelines and policies, as well as academic and grey literature relevant to research with YPLWH across key areas: children and YPLWH, people living with HIV, biological sampling and biobanking, and research in resource-limited settings.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/18/2020 - 5/30/2024
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	Addressing HIV drug resistance research gaps in a cohort of perinatally infected Kenyan children and adolescents
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai), Joseph Hogan (Brown University), Vladamir Novitsky (Miriam Hospital)
Study Type	Prospective
Specific Aim(s)	Aim 1: Investigate genotype-phenotype correlations in HIV-1 subtypes A, C and D. Aim 2: Evaluate etiologies for treatment failure in the presence of a 'susceptible genotype'. Aim 3: Evaluate etiologies for treatment success in the presence of a 'resistant genotype'.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/27/2021 - 5/31/2024
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	An Overview of the Mental Health Care System in 4 Counties in Western Kenya: Findings from an Assessment Using the World Health Organization's Assessment Instrument for Mental Health Systems (WHO-AIMS)
Principal Investigator(s)	Edith Kwobah (Moi Teaching and Referral Hospital)
Collaborator(s)	Matthew Turissini (Indiana University), Florence Jaguga (Moi Teaching & Referral Hospital), Julius Barasa, Richard Matundura, Joyce Nato (World Health Organization)
Study Type	Cross-Sectional
Specific Aim(s)	To collect systems-level mental health care data using the WHO-AIMS in Uasin Gishu, Bungoma, Trans-Nzoia and Busia Counties in western Kenya.
Site(s)	Bungoma, Busia, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	07/02/2020 - Ongoing
Sponsor(s)	None.
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. No update provided for the current reporting period.

Study Title	APPROACH Study
Principal Investigator(s)	Hussein Elias (Moi University)
Collaborator(s)	Eric Finkelstein (Duke University)
Study Type	Prospective
Specific Aim(s)	To understand the perspectives of patients with advanced cancer regarding their quality of life and end of life care. We amended our sample size to 217 patients with stage IV admitted at the inpatient and outpatient clinic. All patients and races will be included in the study as long as they seek treatment at MTRH during the study period, meet the inclusion criteria and consent to participate in the study.
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/1/2021 - 12/31/2021
Sponsor(s)	Duke Global Health
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. No update provided for the current reporting period.

Study Title	Assessing Implementation of Delivering Community-based, Peer-led Interventions for Mental Health Problems among Youth in Eldoret, Kenya
Principal Investigator(s)	Matthew Turissini (Indiana University)
Collaborator(s)	Dr Edith Kwobah, Consultant Psychiatrist, Department of Mental Health, Moi Teaching and Referral Hospital. Dr Florence Jaguga, Consultant Psychiatrist, Department of Mental Health, Moi Teaching and Referral Hospital. Dr Eve Puffer, Assistant Professor, Psychology & Neuroscience, Duke Global Health Institute, Duke University. Ali Giusto, Postdoctoral Fellow, Global Mental Health, Columbia University, Dr Edith Apondi, Associate Professor of Pediatrics, Moi Teaching and Referral Hospital. Julius Barasa, Medical Psychologist, Project Coordinator, AMPATH SIMHS Program. Joseph Binayo, Social worker, Family Health Options Kenya. Dr. Mary A. Ott, Professor, Department of Pediatrics, Indiana University
Study Type	Prospective
Specific Aim(s)	1. To pilot a community-based peer-led screening process for internalizing mental health problems among youth in Eldoret. a) To screen for mental health problems in adolescents via peer mentors (18-24 years) using the SDQ, YTP, PHQ-9, and GAD-7. b) To describe the Reach, Effectiveness, Adoption, Implementation, and Maintenance of the screening process. 2. To pilot a community-based peer-led PST intervention for mental health problems among youth in Eldoret. a) To train and supervise peer mentors in delivering 5 sessions of low-intensity, evidence-based PST for adolescents who screened positive for mental health problems. b) To assess the Reach, Adoption, preliminary Effectiveness, Implementation, and Maintenance of the PST at multiple levels.
Site(s)	Uasin Gishu
Project Period	1/1/2022 - 12/31/2024
Sponsor(s)	Indiana CTSI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Bridging Income Generation with Group Integrated Care (BIGPIC)
Principal Investigator(s)	Rajesh Vedanthan (New York University)
Collaborator(s)	Jemima Kamano (Moi University), Violet Naanyu (Moi University), Sonak Pastakia (Purdue University), Chesoli Cleophas Wanyonyi (Moi University), Benjamin Andama (AMPATH), Diana Menya (Moi University), Eric Finkelstein (Duke University), Gerald Bloomfield (Duke University), David Edelman (Duke University), Joseph Hogan, Brown University, Stavroula Chrysanthopoulou (Brown

	University), Carol Horowitz (Icahn School of Medicine at Mount Sinai), Valentin Fuster (Icahn School of Medicine at Mount Sinai)
Study Type	Prospective
Specific Aim(s)	Aim 1: Identify the contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. Aim 2: Evaluate the effectiveness of group medical visits and microfinance groups for CVD risk reduction among individuals with diabetes or at increased risk for diabetes, by conducting a four-arm cluster randomized trial comparing: 1) usual clinical care; 2) usual clinical care plus microfinance groups only; 3) group medical visits only (no microfinance); and 4) group medical visits integrated into microfinance groups. The primary outcome measure will be one-year change in systolic blood pressure (SBP), and a key secondary outcome will be change in QRISK2 CVD risk score, which has been validated for Black Africans. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial, in terms of costs per unit decrease in SBP, per percent change in CVD risk score, and per disability-adjusted life year saved. 1. Study Population: Enrollment remains closed for this study. 2890 individuals (69.9% women) were enrolled (708 UC, 709 MF, 740 GMV, and 733 GMV-MF). 2. Study end date: The anticipate study end date is now September 30th, 2022.
Site(s)	Busia, Kisumu, Trans Nzoia, Uasin Gishu
Project Period	4/1/2015 - 9/30/2022
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	Chamas for Change: Adapting a community-based peer-support and health education model for pregnant and parenting adolescents in Kenya
Principal Investigator(s)	Julia Songok (Moi University)
Collaborator(s)	Laura J. Ruhl (Indiana University), Lauren Y. Maldonado (USC), Michael Scanlon (Indiana University), Julie Thorne (University of Toronto), Edith Apondi (MTRH), Astrid Christoffersen-Deb (University of British Columbia)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To adapt the Chamas for Change model and curriculum for community-based, peer-support groups to specifically meet the needs of pregnant adolescents, adolescent mothers, and their children. Aim 2: To assess the feasibility and acceptability of an adapted adolescent Chamas for Change program; Aim 3: To assess the impact of participation on maternal, newborn, and child health outcomes, psychosocial outcomes (i.e. mental health, social support), school re-enrollment,

	and financial stability among adolescent participants; and Aim 4: To develop a case study to inform possible adaptations of the Chamas for Change model for adolescents to a North American context. For Phase II of the study this includes pregnant and parenting adolescents aged 15-19 with children aged 6 months or below and not only pregnant adolescents as initially stated.
Site(s)	Busia, Trans Nzoia, Uasin Gishu
Project Period	11/4/2019 - ongoing
Sponsor(s)	Indiana CTSI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. No update provided for the current reporting period.

Study Title	Chamas for Change: Validating an integrated community-based strategy of peer support in pregnancy and infancy
Principal Investigator(s)	Julia Songok (Moi University)
Collaborator(s)	Laura Ruhl (Indiana University), Astrid Christoffersen-Deb (University of British Columbia)
Study Type	Prospective Randomized Controlled Trial
Specific Aim(s)	Validate Chama cha MamaToto as a scalable and effective population-wide strategy to rapidly and sustainably achieve high coverage of facility delivery, quality antenatal and postnatal care, long-term FP and EBF. The primary target was to demonstrate a 30% decrease in maternal (MMR), perinatal (PNR), and newborn (NMR) mortality rates.
Site(s)	Trans Nzoia
Project Period	11/1/2017 – 12/31/2020
Sponsor(s)	Grand Challenges Canada-Saving Lives at Birth
Status	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	Clinical Assessment for Retention and Engagement (CARE Study)
Principal Investigator(s)	Leslie Enane (Indiana University)
Collaborator(s)	Edith Apondi (Moi University), Rachel Vreeman (Mount Sinai), Winstone Nyandiko (Moi University)
Study Type	Cross-Sectional

Specific Aim(s)	Aim 1: Refine a conceptual model for adolescent disengagement from HIV care in East Africa. Aim 2: Develop and pilot an instrument to assess adolescent risk for disengagement from HIV care - the Clinical Assessment for Retention and Engagement (CARE). Aim 3: Develop an evidence-based algorithm to support clinical evaluation and intervention for adolescents at risk for disengagement.
Site(s)	Bungoma, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	10/25/2018 - ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Co-Benefits of Co-Delivery of Long-Acting Antiretrovirals and Contraceptives
Principal Investigator(s)	Rena Patel (University of Washington)
Collaborator(s)	Edwin Were (Moi University), Beatrice Jakait (MTRH), Edith Apondi (MTRH), Caitlin Bernard (Indiana University), Kimberly Scarsi (University of Nebraska Medical Centre), David Erickson (Oregon Health & Science University), Kenneth Sherr (University of Washington), Deborah Donnell (University of Washington), Randy Stalter (University of Washington), Catherine Ngugi (NASCOP)
Study Type	Prospective
Specific Aim(s)	Aim 1: To collect foundational data to better inform design of an effectiveness-implementation trial. Aim 1a: To determine if combined cabotegravir/rilpivirine injectable use has bidirectional drug-drug interactions with injectable (depot medroxyprogesterone acetate [DMPA]) or implantable (etonogestrel or levonorgestrel) contraceptives. Aim 1b: To qualitatively explore points of convergence and divergence, preferences and values, and health systems readiness around wider-scale co-delivery of LA ART and contraceptives. Aim 2: To evaluate the impact of clinic-provided, co-delivery of LA ART and contraceptives among AGYWLHIV. Aim 2a: To evaluate the impact on effectiveness outcomes of HIV treatment (viral suppression and adherence/persistence) and contraception (uptake and continuation rates). Aim 2b: To evaluate the impact on implementation outcomes of acceptability, feasibility, and fidelity.
Site(s)	MTRH
Project Period	4/1/2021 – 3/31/2026
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Comparison of Nutritional status of children aged 5 to 59 months in community-based education and service (COBES)-AMPATH and non AMPATH centres post covid-19
Principal Investigator(s)	Arthur Kwena (Moi University)
Collaborator(s)	J. Ballidawa (Moi University), K. Taylor (Notre Dame), M. McDowell (Notre Dame), S. Mining (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	To determine the nutritional status of children in selected COBES centres post Covid-19 and compare the nutritional status in AMPATH and non-AMPATH centres.
Site(s)	Bungoma, Busia, Elgeyo Marakwet, Kakamega, Nandi, Trans Nzoia, Uasin Gishu
Project Period	1/1/2014 - ongoing
Sponsor(s)	None
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	Compassion Fatigue, Satisfaction and Burnout Among Healthcare workers in the Context of the COVID 19 pandemic in Uasin Gishu County
Principal Investigator(s)	Edith Kwobah (Moi Teaching and Referral Hospital)
Collaborator(s)	Jane Kariuki (Moi Teaching and Referral Hospital), Florence Jaguga (Moi Teaching and Referral Hospital)
Study Type	Cross-Sectional
Specific Aim(s)	1. To determine the prevalence of compassion fatigue, compassion satisfaction and burnout among health care workers in the context of the COVID 19 pandemic in Uasin Gishu County; 2. To determine social demographic factors associated with development of compassion fatigue, compassion satisfaction and burnout among health care workers in the context of the COVID 19 pandemic Uasin Gishu County; 3. To determine the association between health care workers' previous training in disaster/ emergency response and development of compassion fatigue and burnout among health care workers in the context of the COVID 19 pandemic in Uasin Gishu County
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/12/2021-Ongoing

Sponsor(s)	Mental Health RDF funds
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	Data Science for Decision Support in the HIV Care Cascade
Principal Investigator(s)	Joseph Hogan (Brown University), Ann Mwangi (Moi University), Hamish Frasier (Brown University)
Collaborator(s)	Juddy Wachira (Moi University), Edwin Sang (AMPATH), Lameck Diero (Moi University), Jonathan Dick (Indiana University), Rami Kantor (Brown University), Jonathan Teich (Brigham and Women's Hospital), Arman Oganisian (Brown University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Develop and validate statistical machine learning models and algorithms for clinical and programmatic decision support. Aim 2. Develop, implement and field test decision support and data visualization tools to enhance data-driven decision making by physicians and program managers. Aim 3: Conduct evaluation of the impact and efficacy of the clinical decision support tools in Kenya.
Site(s)	All AMPATH sites
Project Period	11/1/2021 - 10/31/2026
Sponsor(s)	NIH
Status	Ongoing -- The first phase of the study deals with development of statistical methodology. That work has started. No update provided for the current reporting period.
Study Title	Determining The Frequency of Cytogenetic Abnormalities among Multiple Myeloma Patients in Kenya using an Artificial Intelligence-based Approach: A Retrospective Cohort Study
Principal Investigator(s)	Teresa Lotodo (Moi University)
Collaborator(s)	Mercy Atieno Oduor (AMPATH), Kelvin Manyega (Kabarak University), Beatrice Melly (MTRH), Austin Omondi (AMPATH), Diana Flora Namaemba (AMPATH), Yvette Oyolo (AMPATH), Ola Landgren (University of Miami), Francesco Maura (University of Miami)
Study Type	Retrospective
Specific Aim(s)	Aim 1. To determine, by using AI methods, the frequency of suspected cytogenetic abnormalities in multiple myeloma patients at diagnosis based on scanned images of H&E and CD138 stained slides. Aim 2. To correlate the AI classification of MM patients at diagnosis with their survival.

Site(s)	Uasin Gishu (MTRH)
Project Period	10/1/2021 - 12/1/2022
Sponsor(s)	University of Miami
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Developing Capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct
Principal Investigator(s)	Edwin Were (Moi University)
Collaborator(s)	Jepchirchir Kiplagat (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Estimate the prevalence of and explore stakeholder perceptions on research misconduct and how it can best be addressed in Kenya. Aim 2: Explore the perceptions on capacity to prevent, detect and manage research misconduct and the perceived critical components of a model framework for managing research misconduct. Aim 3. Develop and pilot test a model framework for detecting and managing research misconduct.
Site(s)	Kisumu, Moi Teaching and Referral Hospital, KNH, Research Ethics Committees in Kenya
Project Period	8/1/2017 - 7/31/2022
Sponsor(s)	NIH-FIC
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	EA-IeDEA: A longitudinal survey study of the impact of COVID-19 preparedness and response efforts on people living with HIV in East Africa
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Lameck Diero (Moi University), Constantin Yiannoustos (Indiana University School of Medicine), Aggrey Sameere (College of Health Sciences Makerere University)

Study Type	Longitudinal observational cohort study
Specific Aim(s)	Aim 1: Assess COVID-19 related knowledge, attitudes, and beliefs among a diverse cohort of people living with HIV in East Africa. Aim 2: Describe the impact of COVID-19 on socio-economic well-being, health status, health services utilization, and health behaviors among a diverse cohort of people living with HIV in East Africa.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/9/2020 - ongoing
Sponsor(s)	None
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	EA-IeDEA: ACE Study
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Kara Wools-Kaloustian (Indiana University), Edith Apondi (MTRH), Batya Elul (Columbia University), Rami Kantor (Brown University), Samuel Ayaya (Moi University), Giorgos Bakoyannis (Indiana University), Leslie Enane (Indiana University), Zachary Kwena (FACES -KEMRI)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Describe the engagement status (engaged, LTP with care disengagement, LTP with re-engagement, or LTFU), virologic suppression status (viral suppression or viral non-suppression), and vital status (alive, dead, or LTFU) for PIA. Aim 2: Provide in-depth characterization of the populations of PIA engaged in and disengaged from care, including describing current HIV care-related characteristics (ART regimen, adherence to treatment, experiences of HIV-related stigma, HIV care preferences); virologic outcomes (viral suppression, viral failure, and drug resistance patterns); pregnancy status; and mental and behavioral health characteristics (depression, substance use). Aim 3: Describe virologic, mental and behavioral health outcomes and HIV care preferences by HIV care status (engaged, LTP with care disengagement, LTP with re-engagement, or LTFU). Aim 4: Identify patient-level factors (including clinical characteristics, mental and behavioral characteristics, and HIV care preferences) associated with HIV care status (engaged, LTP with care disengagement, or LTP with re-engagement), viral suppression, and death.
Site(s)	Moi Teaching and Referral Hospital, Trans Nzoia
Project Period	8/1/2018 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	EA-IeDEA: Adolescent and Young Adult Network of IeDEA (AYANI)
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Dr.Edith Apondi, Moi University School of Medicine; Kara Wools-Kaloustian, Indiana University School of Medicine; Dr. Zachary Kwena, The Family AIDS Care and Education Services (FACES); Dr. Batya Elul, Columbia University Medical Center, NY, USA; Dr. Leslie Enane, Indiana University School of Medicine, Indianapolis, IN, USA: Prof. Winstone Nyandiko, Moi University School of Medicine
Study Type	Prospective
Specific Aim(s)	1: Describe care engagement patterns (retention, losses-to-follow up), transition indicators (e.g., self-care, socio-demographic data), viral suppression, and mortality among the group of ALWH, both prior to cohort formation and at follow-up. 2: Examine the correlates of key clinical and socio-demographic factors with retention and viral non-suppression among ALWH. Factors to be assessed include: gender, HIV-disclosure age, transitions in care, self-reported adherence, pregnancy, stigma, depression, anxiety, trauma, sexual risk behaviors, and substance use. 3: To assess the feasibility of establishing a multiregional cohort of ALWH for in-depth data collection. Feasibility measures include numbers of ALWH eligible, enrolled and retained.
Site(s)	Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia
Project Period	7/1/2021 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	EA-IeDEA: Jozi Study (Determining Long-Term Clinical Outcomes for HIV-Affected Mother-Infant Dyads in Western Kenya: Sub-Study to the Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study)
Principal Investigator(s)	Jimmy Carlucci (Indiana University)
Collaborator(s)	Audrey Chepkemoi (Kenyan Co-PI; Moi University) John Humphrey (parent MANGO study PI; Indiana University) Kara Wools-Kaloustian (EA-IeDEA PI overseeing MANGO and sub-studies; Indiana University) Rena Patel (University of Washington) Megan McHenry (Indiana University) Edwin Were (Moi University)
Study Type	Prospective
Specific Aim(s)	SA-1: Ascertain maternal outcomes in the prevention of mother-to-child transmission of HIV (PMTCT) service continuum, with emphasis on virologic outcomes for pregnant and postpartum women living

	with HIV (WLHIV). Hypothesis 1: Virologic failure will be more common in WLHIV who are lost to follow-up (LTFU) from the PMTCT program compared to WLHIV who are retained in care. SA-2: Ascertain infant outcomes in the PMTCT service continuum, with emphasis on early infant diagnosis (EID) and definitive determination of HIV status of HIV-exposed children after cessation of breastfeeding. Hypothesis 2: Favorable maternal virologic and retention outcomes will be associated with completion of EID testing, definitive testing after cessation of breastfeeding, and HIV seronegative status (i.e., mitigation of vertical transmission) among HIV-exposed infants.
Site(s)	Uasin Gishu (MTRH)
Project Period	8/1/2021 - 7/31/2023
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	## EA-IeDEA: Main Study
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Constantin Yiannoutsos (Indiana University), Lameck Diero (Moi University), Samuel Ayaya (Moi University)
Study Type	Retrospective
Specific Aim(s)	To collaborate with clinical sites to identify and define key variables, harmonize and effectively analyze the data to generate large datasets.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu, West Pokot
Project Period	8/1/2006 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	## EA-IeDEA: Measuring Adverse Pregnancy and Newborn Outcomes (MANGO)
Principal Investigator(s)	Edwin Were (Moi University)
Collaborator(s)	Rena Patel, Julia Songok, Bett Kipchumba, Audry Chepkemboi, Wycliffe Kosgei, Joy Marsha, Catlin Bernard, Beverly Musick, Laura Oyiengo, Elvis Oyungi, Molly MacPheron, Meghan McHenry, Edward

	Leichty, Ushma Mehta, Emma Kalk, Amy Slogrove, Andrew Boulle, Mary-Ann Davieis, Constantine Yiannoultsos, Kara Wools-Kaloustian, Jimmy Carlucci, and Audrey Chepkemoi
Study Type	Mixed prospective and retrospective cohort study
Specific Aim(s)	1. Determine event rates for adverse pregnancy outcomes, congenital abnormalities (CAs) and other abnormal conditions in infants born to HIV+ and HIV- women and determine the associations between adverse pregnancy and infant outcomes and ART exposures during conception and pregnancy 2. To create standardized protocols and data exchange standards within IU and IeDEA. By leveraging the existing and extensive IeDEA Data Exchange Standard (DES) and creating a Data Standards Task Force and a Data Coordinating Center for PV, we will add new tables and expand existing ones, as necessary, to include new concepts and fields responsive to the needs of pharmacovigilance among pregnant women.
Site(s)	Uasin Gishu
Project Period	8/3/2020 - 7/31/2025
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	EA-IeDEA: Networks In Kenya
Principal Investigator(s)	Jennifer Syvertsen (University of California, Riverside, USA)
Collaborator(s)	Lukoye Atwoli (Moi University/Aga Khan University), Edith Kwobah (MTRH), Suzanne Goodrich (Indiana University), Karla D Wagner (University of Nevada), Maurice Aluda (KEMRI/FACES), Jayne Kulzer (UCSF), Kara Wools-Kaloustian (Indiana University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To examine how social network factors (e.g., network size, structure, composition) are associated with patterns of alcohol and other drug use (AOD), sexual behaviors, engagement in care, and HIV clinical outcomes among a sample of EA IeDEA-affiliated clinic patients who screen positive for alcohol and/or drug use and a comparison group. Aim 2: To qualitatively describe the nature and overlap of key relationships (e.g., risky and supportive) within patients' networks and assess their associations with HIV outcomes. Aim 3: To use mixed methods to explore the feasibility and acceptability of developing a social network intervention to reduce AOD risk behaviors, improve HIV clinical outcomes, and increase linkages to testing and care among people who use alcohol and/or drugs in East Africa.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/29/2019 - ongoing
Sponsor(s)	NIH-NIAID

Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	EA-IeDEA: NIDA Study
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Lameck Diero (Moi University), Suzanne Goodrich (Indiana University), Edith Kwobah (MTRH), Patrick Oyaro (FACES/RCTP/KEMRI), Maurice Aluda (FACES/RCTP/KEMRI), Jayne Kulzer (UCSF)
Study Type	Prospective
Specific Aim(s)	Aim 1: Estimate the prevalence of hazardous alcohol consumption in patients enrolling in HIV- care and compare their baseline characteristic with those of non-drinkers. Aim 2: Compare clinician and research assistant collected AUDIT screening data at one clinic within the East African IeDEA consortium. Aim 3: Assess the impact of hazardous drinking on patient outcomes including time to antiretroviral therapy (ART) initiation, medication adherence, retention in care, and death at 6 months and again at 24-36 months. Aim 4: Assess strategies utilized by patients to address their hazardous alcohol use.
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/31/2017 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	EA-IeDEA: PHQ 9 Study
Principal Investigator(s)	Marcel Yotebieng (Albert Einstein College of Medicine)
Collaborator(s)	Kathryn Lancaster (Ohio State University); Lukoye Atwoli (Moi University); Jennifer Syvertsen (University of California, Riverside), Kara Wools-Kaloustian (Indiana University), et al.
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Determine the region-specific differences in the quality of measurement afforded by the PHQ-9. Aim 2: Determine the dimensionality of PHQ-9 and assess whether a different scoring system or cut-point is needed among PLWH. Aim 3: Describe how PLWH in both region express mental distress and determine whether reformulation/adaptation of questions in PHQ-9 will improve its performance
Site(s)	Moi Teaching and Referral Hospital
Project Period	11/23/2020 - ongoing

Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	EA-IeDEA: PMTCT Plus Study: Improving Estimates of Mother-to-Child Transmission in Western Kenya: A Mixed Methods Prospective Cohort Study
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Bett Kipchumba, Marsha Alera, Libby Pfeiffer, Julia Songok, Winfred Mwangi, Wycliffe Kosgei, Beverly Musick, Constantin Yiannoutsos, Juddy Wachira, Kara Wools Kaloustian
Study Type	Prospective
Specific Aim(s)	Aim 1. Determine the barriers and enhancers to retention in care and viral suppression for postpartum women. Sub-Aim 1a: identify factors influencing retention and viral suppression using (i) statistical methods for observational data that incorporate LTFU outcomes, and (ii) qualitative interviews among 30 postpartum women and 15 of their male partners; Sub-Aim 1b: determine the prevalence of HIV resistance and its association with viral non-suppression by genotyping postpartum blood samples with detectable viremia and stored samples collected during pregnancy and earlier postpartum. We are now conducting follow-up study visits at 3 years postpartum for all enrolled women and infants.
Site(s)	Busia, Trans Nzoia, Uasin Gishu
Project Period	2/1/2021 - 2/1/2022
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	EA-IeDEA: Predicting Neurodevelopmental Risk in Children born to Mothers Living with HIV in Kenya: Sub-Study to the Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study
Principal Investigator(s)	Megan McHenry (Indiana University)

Collaborator(s)	Eren Oyungu-Moi University Rachel Vreeman-Mt Sinai Winstone Nyandiko-Moi University Patrick Monahan-Indiana University Alka Khaitain-Indiana University Zeruesenay Desta-Indiana University Amy Slogrove-Stellenbosch University Rena Patel-Univ. of Washington
Study Type	Longitudinal follow up of the enrolled study participants for 2 years.
Specific Aim(s)	Evaluate potential risk factors for worse ND outcomes in young Kenyan children who are HEU and HUU Compare ND outcomes between 24-month-old children who are HEU and HUU in Kenya Create a risk assessment tool to predict which children are at risk for worse ND outcomes at 24 months
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/1/2021-6/30/2026
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	## EA-IeDEA: Syndemics Study
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Suzanne Goodrich (Indiana University), Jennifer Syvertsen (University of California Riverside), Jayne Kulzer (UCSF), Maurice Aluda (FACES/RCTP/KEMRI), Lukoye Atwoli (Moi University), Edith Kwobah (MTRH)
Study Type	Prospective
Specific Aim(s)	Aim 1: Identify community and clinic-based services available for treatment of substance use and mental health disorders in the three research sites. Aim 2: Determine the prevalence of substance use (drug and alcohol) and mental health disorders in patients enrolling into care. Aim 3: Assess the impact of substance use, mental health disorders and dual diagnoses on patient adherence and retention in the cascade. Aim 4: Conduct qualitative interviews with a sub-sample of cohort patients to explore access, use, and experiences with substance use and mental health services.
Site(s)	Moi Teaching and Referral Hospital
Project Period	12/17/2018 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	EA-IeDEA: The Desire to Avoid Pregnancy Post-partum (DAPP Study)
Principal Investigator(s)	Wycliffe Kosgei (Moi Teaching and Referral Hospital)
Collaborator(s)	Caitlin Bernard (Indiana University)
Study Type	Tool development/validation
Specific Aim(s)	The aims of this study are to: 1. Conduct focus group discussions (FGDs) and field-testing, we will engage women and providers living in western Kenya to modify the existing scale items and responses and test the performance of these modified items to develop a final adapted DAP scale. 2. Evaluate the psychometric performance of the adapted DAP scale, including internal consistency, confirmatory fit to a one-factor model, and predictive validity, including whether DAP scale score predicts contraceptive use postpartum. 3. Compare the performance of the adapted DAP scale between Women living with HIV vs Women Not Living with HIV. We will leverage the cohort of women enrolled in the MANGO-Kenya study, which plans to recruit up to 400 women living with HIV and 400 women not living with HIV enrolling in ANC at MTRH. The 800 participants will be contacted and asked to participate in this sub-study during the postpartum period.
Site(s)	Uasin Gishu (Moi Teaching and Referral Hospital)
Project Period	9/7/2020 – ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Enhancing Preventive Therapy of Malaria in children with Sickle Cell Anemia (SCA) in East Africa (EPiTOMISE)
Principal Investigator(s)	Festus Njuguna (Moi University)
Collaborator(s)	Steve Taylor (Duke University), Wendy O'Meara (Duke University)
Study Type	Randomized, three-arm, open-label, clinical trial
Specific Aim(s)	Aim 1: Compare the efficacy of daily Proguanil with that of monthly sulfadoxine/pyrimethamine-amodiaquine (SP-AQ) or monthly dihydroartemisinin-piperaquine (DP) to prevent P. falciparum malaria in children with sickle cell. Aim 2: Compare the efficacy of daily Proguanil, monthly SP-AQ, and monthly DP to prevent painful events in children with sickle cell anemia. Aim 3: Compare the impact of malaria chemoprophylaxis regimens on molecular markers of parasite drug resistance to Proguanil, SP-AQ, and DP.

Site(s)	Homa Bay
Project Period	6/1/2016 - 2/28/2021
Sponsor(s)	NIH-NHLBI
Status	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy
Principal Investigator(s)	Rena Patel, University of Washington
Collaborator(s)	Beatrice Jakait (Moi Teaching and Referral Hospital), Caitlin Bernard (Indiana University)
Study Type	Retrospective
Specific Aim(s)	To assess the relative effectiveness of Levonorgestrel-based (LNG) implants with concomitant efavirenz-based ART among a random subsample of HIV-positive women attending AMPATH-supported HIV treatment facilities using chart reviews and phone interviews.
Site(s)	All AMPATH sites.
Project Period	5/1/2016-1/25/2021
Sponsor(s)	NIH – NIAID
Status	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	Ethnic Specific Risk Stratification in Early Pregnancy for Identifying Mothers at Risk of Gestational Diabetes Mellitus in Eldoret Kenya
Principal Investigator(s)	Wycliffe Kosgei (Moi Teaching and Referral Hospital)
Collaborator(s)	Astrid Christoffersen (University of British Columbia), Sonak Pastakia (Purdue University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence rates of GDM in rural and urban populations. Aim 2: To assess the impact of the risk factors of interest (age, BMI and family history) for GDM in early pregnancy. Aim 3: To develop and validate of composite risk score for GDM with the risk factors of interest and/or point-of-care HbA1c.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu

Project Period	6/13/2016 – ongoing
Sponsor(s)	UK Medical Research Council; Warwick University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	Evaluating reproductive and HIV outcomes and decision-making among HIV-positive women on dolutegravir: A prospective, observational cohort at AMPATH, Kenya
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Rena Patel, Mercy Maina, Julie Thorne, Beatrice Jakait, Caitlin Bernard
Study Type	Retrospective analysis of AMRS data and telephone surveys
Specific Aim(s)	Aim 1. To evaluate key reproductive health and HIV outcomes among women initially on DTG-containing ART. Aim 2: To investigate factors facilitating provider and patient decision-making for HIV-infected women choosing between ART and contraceptive choices.
Site(s)	
Project Period	7/9/2020 – 6/30/2022
Sponsor(s)	NIH; Indiana University
Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	Evaluation of Chronic Hypoxemia from Cardiopulmonary Disease Among Patients Admitted to a Referral Hospital in Western Kenya and Their Perspectives on Oxygen Use
Principal Investigator(s)	Neelima Navuluri (Duke University)
Collaborator(s)	David Lagat (Moi University), Peter Kussin (Duke University), Lameck Diero (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Determine the prevalence of chronic hypoxemia from cardiopulmonary disease and the associated in-hospital mortality rate among patients admitted to Moi Teaching and Referral Hospital (MTRH) inpatient medicine wards from August 2019 - June 2021. Aim 2: Characterize patients with chronic hypoxemia admitted to MTRH by determining demographic and environmental risk factors,

	associated co-morbidities such as HIV, and underlying etiologies. Aim 3: Assess quality of life measures among patients with chronic hypoxemia and their perspectives on oxygen therapy.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	9/1/2019 – ongoing
Sponsor(s)	NIH-Fogarty
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Feasibility and acceptability of Enhanced Patient Care (EPC) for adult HIV patients with unsuppressed viral loads in western Kenya
Principal Investigator(s)	Juddy Wachira (Moi University)
Collaborator(s)	Becky Lynn Genberg (John Hopkins University), Ira Wilson (Brown University), Abraham M. Siika (Moi University), Omar Galarraga (Brown University), Paula Braitstein (University of Toronto) Ann Mwangi (Moi University), Sylvestor Kimaiyo (Moi University), Jonathan Dick (Indiana University), Michael Bart Laws (Brown University)
Study Type	Randomized Controlled Trial
Specific Aim(s)	Aim 1. Determine the impact of system-level factors on patient engagement (clinic adherence) among adult HIV patients. Aim 2. Assess the feasibility and acceptability of enhanced patient care (EPC) clinics for promoting patient engagement (clinic adherence) among patients with unsuppressed viral load (≥400). Aim 3. Determine the cost effectiveness of EPC for engagement of patients with unsuppressed viral load.
Site(s)	Busia
Project Period	7/3/2017 - 12/30/2022
Sponsor(s)	NIH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya
Principal Investigator(s)	Omar Galárraga (Brown University)

Collaborator(s)	Becky Lynn Genberg (Johns Hopkins University), Juddy Wachira (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To evaluate the extent to which integrated community-based HIV care with group microfinance affects retention in care and viral suppression among PLHIV in rural western Kenya using a pragmatic cluster randomized intervention design of 40 existing (majority HIV+) microfinance groups to receive microfinance plus either: (A) integrated community-based HIV care, or (B) standard care. Aim 2: To identify specific mechanisms through which microfinance and integrated community-based care impact viral suppression. Aim 3: To assess the cost-effectiveness of microfinance and integrated community-based care delivery to maximize future policy and practice relevance of this promising intervention strategy.
Site(s)	Busia, Trans Nzoia
Project Period	7/5/2019 - 4/30/2024
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	HIV-related outcomes at the AMPATH Drug Resistance Clinic in Kenya
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Shamim Ali, Bilal Syed, Suzanne Goodrich, Celia Ngetch, Beatrice Jakait, Rami Kantor, Adrian Gardner
Study Type	Retrospective
Specific Aim(s)	Aim 1: Describe the clinical characteristics of patients attending the AMPATH HIV Drug Resistance Clinic, including the prevalence of drug resistance mutations. Aim 2: Describe the virologic and ART outcomes of patients failing second and third-line ART, including the proportion of patients who achieve viral suppression following enrollment in the clinic and the proportion experiencing an ART regimen change.
Site(s)	Uasin Gishu
Project Period	3/3/2020 – 6/30/2022
Sponsor(s)	None
Status	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	IeDEA: Sentinel Research Network (SRN)

Principal Investigator(s)	Niharika Samala (Indiana University)
Collaborator(s)	Kara Wools-Kaloustian, Lameck Diero, Suzanne Goodrich, Edith Kwobah, Mercy Karoney, Ayub Barasa, Alexa Monroy, Samir Gupta, Fatuma Some
Study Type	Prospective
Specific Aim(s)	To establish a network of research sites, the Sentinel Research Network (SRN), and to capture and analyze standardized data among PLHIV in LMICs. Through this network, we further seek to implement studies on cardiovascular risk factors, mental health, alcohol and other substance use disorders, as well as liver disease prevalence and associated factors among PLHIV accessing care in LMICs.
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/1/2020 - 7/31/2022
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	Impact of COVID-19 on adolescents living with HIV in Kenya
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai)
Study Type	Prospective
Specific Aim(s)	Aim 1: Investigate changes in ART adherence, mental health and socio-economic well-being related to COVID-19, and their association with viral failure and DR outcomes in Kenyan ALWH. Aim 2: Estimate exposure to COVID-19 and association with viral failure and DR outcomes among Kenyan ALWH enrolled in the parent grant.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/20/2020 - 5/31/2024
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Impact of Infection Prevention Care Bundles on Surgical Site Infections Post Cesarean Section in Moi Teaching and Referral Hospital
Principal Investigator(s)	Adrian Gardner (Indiana University)
Collaborator(s)	Wycliffe Kosgei (MTRH), Faith Sila (MTRH), Jackline Opondo (MTRH), Shem Kinara (MTRH), Betty Rop (MTRH), Sarah Esendi (MTRH), Mercy Jelimo (MTRH), Vitalis Orango (MTRH), Luke Sartino (IU Health), Catherine Sartino (IU Health), Marnie Sieber (IU Health), William Fadel (IU Health), Kristen Kelley (IU Health), Bilal Jawed (Indiana University)
Study Type	Pre-post study design
Specific Aim(s)	The aims of this study are: 1. Identify the current healthcare provider antimicrobial prescribing patterns for patients undergoing cesarean section and implement cesarean section surgical site surveillance at MTRH. 2. Determine the antimicrobial susceptibility patterns in cesarean section wound infections and compare against antimicrobials prescribed. 3. Identify the baseline prevalence of surgical site infections and analyze the short- and long-term complications of SSI after cesarean section 4. Calculate and analyze the prevalence of health disparities in patients having cesarean section complications 5. Based on objectives 1-4, develop a surgical site infection practice bundle and policy designed around pertinent risk factors: determinants of health, antimicrobial use, modifiable risk factors and clinical gaps in care and implement surgical site infection bundle and policy and evaluate outcomes.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	1/1/2022 -
Sponsor(s)	Pfizer
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Implementing a Model of Improved Care for Infectious Diseases and Antibiotic Stewardship across Multiple Levels of the Health System in Western Kenya
Principal Investigator(s)	Charles Kwobah (Moi University)
Collaborator(s)	Shamim Ali - Moi University Suzanne Goodrich - Indiana University Adrian Gardner - Indiana University
Study Type	Prospective

Specific Aim(s)	The aim of this project is to optimize appropriate antibiotic use in order to improve clinical outcomes while minimizing unintentional consequences of use, including the emergence of antimicrobial resistance.
Site(s)	Bungoma, Elgeyo Marakwet, Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	10/1/2019 – 9/30/22
Sponsor(s)	Pfizer Foundation
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Integrating hypertension and diabetes screening and management with HIV care services for older adults: Feasibility study
Principal Investigator(s)	Jepchirchir Kiplagat (Moi University)
Collaborator(s)	Kara Wools-Kaloustian, Jemimah Kamano, Sonak Pastakia, Violet Naanyu, Rajesh Vedanthan
Study Type	Mixed methods
Specific Aim(s)	Specific aims: To lay the groundwork for integrated HIV and NCD services, this project aims to; i) Determine unmet needs for hypertension and diabetes screening and treatment in OALWH ii) Assess feasibility and acceptability of utilizing AMPATH's HIV care platform to provide diabetes and hypertension screening and treatment services to older adults living with HIV.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	7/1/2021 – 6/30/2022
Sponsor(s)	NIH-Fogarty International Center
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	JSVCT109 "A global multicenter, randomized, double-blind, placebo-controlled, phase III clinical trial to evaluate the efficacy, safety, and immunogenicity of recombinant COVID-19 vaccine (Sf9 cell) for the prevention of COVID-19 in adults aged 18 years and older "

Principal Investigator(s)	Sylvester Kimaiyo (Moi University)
Collaborator(s)	Nicholas Kirui (Moi Teaching and Referral Hospital), Thomas Andale (Moi Teaching and Referral Hospital)
Study Type	Prospective
Specific Aim(s)	1.To evaluate the efficacy of recombinant COVID-19 vaccine (Sf9 cells) in preventing virologically confirmed (PCR positive) symptomatic COVID-19 cases first occurring Ôπ•28 days after completion of 3 vaccination doses, regardless of severity 2. To evaluate the incidence of SAEs, MAAEs and AESIs from Day 0 through 6 months after completion of 3 doses vaccination and the reactogenicity(the incidence of solicited AEs and unsolicited AEs) in all participants.
Site(s)	Elgeyo Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, Vihiga
Project Period	10/4/2021 - 3/31/2023
Sponsor(s)	WestVac Biopharma Co., Ltd. and West China Hospital of Sichuan University
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	Making Inroads to Strengthen the Health of Adolescents (MAISHA)
Principal Investigator(s)	Leslie Enane (Indiana University)
Collaborator(s)	Edith Apondi (Moi University), Rachel Vreeman (Mount Sinai), Winstone Nyandiko (Moi University), Elizabeth Lowenthal (University of Pennsylvania)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1. To quantify missed opportunities along the HIV care cascade among adolescents prior to hospitalization in western Kenya, by examining timing and outcomes of HIV diagnosis, linkage to and retention in care, and viral suppression. (Secondary Aim: To determine the causes of hospitalization and mortality among adolescents with HIV in western Kenya); Aim 2. To define critical barriers contributing to delays or failures in the care cascade, as well as facilitators to care, and to identify areas of potential intervention.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/12/2017 – ongoing
Sponsor(s)	Indiana University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	## Maternal Newborn Health Registry
Principal Investigator(s)	Fabian Esamai (Moi University)
Collaborator(s)	Sherri Bucher (Indiana University), Edward Liechty (Indiana University), Irene Marete (Moi University), Constance Tenge (Moi University)
Study Type	Prospective
Specific Aim(s)	A multicenter (8 sites in 7 countries) prospective, population-based registry which enrolls women during pregnancy and tracks pregnancy, delivery, and postnatal maternal and neonatal outcomes through 42 days postpartum. A vital registry system allows the Global Network to document maternal and neonatal mortality, design trials to address the major causes of poor outcomes, assess the outcome of our interventions, and ultimately, disseminate the results as the basis of public health policy.
Site(s)	Bungoma, Busia, Kakamega
Project Period	10/15/2008 – ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. No update provided for the current reporting period.

Study Title	## Mobile Mental Health Monitoring and Support for Adolescents with HIV in Kenya
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Edith Apondi (MTRH), Bree Weaver (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Assess the feasibility, acceptability, and usability of a cell phone-based intervention to provide mental health services (tele-therapy and tele-peer support) for HIV-infected adolescents in Kenya. Aim 2: Evaluate the user engagement with both the cell phone-based intervention and the clinical care system throughout the monitoring period using counselor reports, usage tracking, and clinical database evaluation. Aim 3: Describe key clinical, mental, and emotional health outcomes for this cohort during the monitoring period, including medication and clinic adherence, viral suppression, depression symptoms and other behavioral or emotional symptom reports, and engagement with support services such as peer support groups.
Site(s)	Uasin Gishu
Project Period	1/1/2017 - 12/31/2018

Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	Multicenter Study of Pomalidomide Monotherapy in HIV-Infected Individuals with Kaposi Sarcoma (KS) in Sub-Saharan Africa (SSA)
Principal Investigator(s)	Naftali Busakhala (Moi University)
Collaborator(s)	Evangeline Njiru, Susan Krown, Samantha Vogt
Study Type	Prospective
Specific Aim(s)	The study objective is to determine if pomalidomide monotherapy induces an antitumor efficacy and whether it is safe and tolerable, in order to justify its further development for treatment of HIV-associated KS in sub-Saharan Africa.
Site(s)	Kisumu, Moi Teaching and Referral Hospital
Project Period	7/15/2021-Ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	NeoInnovate Collaborative Consortium
Principal Investigator(s)	Sherri Bucher (Indiana University)
Collaborator(s)	Saptarshi Purkyastha (Indiana University), Fabian Esamai (Moi University)
Study Type	n/a
Specific Aim(s)	The NeoInnovate Collaborative Consortium is a multi-disciplinary international coalition of faculty, students, and post-graduate trainees led by IU School of Medicine and Alupe University College (Moi University) and partnering with Moi Teaching and Referral Hospital (Kenya), IUPUI, Purdue University, and University of Notre Dame. The Consortium builds, deploys, and evaluates innovative solutions by which to equip, empower, and strengthen health care providers, communities, and health systems. These efforts supply partners and stakeholders with the knowledge, skills, and tools by which to successfully disseminate, implement, scale-up, and sustain evidence-based, life-saving interventions to improve maternal and newborn outcomes.
Site(s)	n/a

Project Period	n/a
Sponsor(s)	None
Status	Preparing grant submissions. No update provided for the current reporting period.

Study Title	Neurodevelopmental Screening in Children Born to HIV-Infected Mothers in Kenya
Principal Investigator(s)	Megan McHenry (Indiana University)
Collaborator(s)	Eren Oyungu (Moi University)
Study Type	Prospective
Specific Aim(s)	AIM 1: Determine and compare the reliability and validity of neurodevelopmental screening tools and assessments for use among children aged 18-36 months in Kenya. The objective for this aim is to identify an optimal screening tool and assessment for use in Kenya. AIM 2: Evaluate neurodevelopmental screening implementation in an existing healthcare system in Kenya. •Sub-aim 2a: Develop a contextualized implementation plan and Sub-aim 2b: Pilot a ND screening program at one MCH clinic in Kenya. In addition, we will assess effectiveness of ND screening, as determined by sensitivity; specificity; and positive and negative predictive values.
Site(s)	Uasin Gishu
Project Period	9/30/2018 - 8/31/2022
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Neuropsychiatric Genetics of African Populations -Psychosis (NEUROGAP-P)
Principal Investigator(s)	Lukoye Atwoli (Aga Khan University)
Collaborator(s)	Gabriel Kigen, Edith Kwobah, Wilfred Emonyi
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To determine the phenotypic presentation of psychotic disorders in African populations. Aim 2: To describe the genetic variation between patients with psychotic disorders and those without in African populations. Aim 3: To examine the association between genetic variation and risk for schizophrenia and bipolar disorder in African populations Aim 4: To provide opportunities for

	training of African scientists in neuropsychiatric genetics research. Target number of participants has since been reviewed to 5,200
Site(s)	Bungoma, Elgeyo Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, West Pokot
Project Period	7/1/2017 - 6/30/2022
Sponsor(s)	Broad Institute of MIT; Harvard University
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	Optimizing HIV treatment monitoring strategies under resource constraints
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Ann Mwangi (Moi University), Lameck Diero (Moi University), Joseph Hogan (Brown University)
Study Type	The research will use previously collected data and blood samples stored from previously IREC approved AMPATH studies.
Specific Aim(s)	1) Develop and apply scalable statistical framework for optimal targeting of gold standard diagnostic tests used to monitor HIV treatment under resource constraints; 2) Apply causal inference techniques to calibrate decision rules using estimated decision utilities; 3) Develop methods to optimize pooling strategies for viral load testing in resource limited settings; 4) To implement and cross validate new algorithms for viral load pooling using samples from drug resistant patients
Site(s)	All AMPATH clinics
Project Period	2/3/2016 – 10/31/2022
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)
Principal Investigator(s)	Valentin Fuster (Mount Sinai)
Collaborator(s)	Jemima Kamano (Moi University), Violet Naanyu (Moi University), Diana Menya (Moi University), Sylvester Kimaiyo (Moi University), Rajesh Vedanthan (NYU Grossman School of Medicine), et al.

Study Type	Prospective
Specific Aim(s)	The objective of this project is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high blood pressure to a hypertension care delivery program, using a combination of qualitative research methods. Aim 2: Evaluate the effectiveness of CHWs equipped with a tailored behavioral communication strategy and a smartphone-based tool in improving linkage and reducing blood pressure among hypertensive patients, by conducting a cluster randomized trial comparing: 1) usual care (CHWs with standard training on recruitment of individuals with any chronic condition); 2) CHWs with an additional tailored behavioral communication strategy; and 3) CHWs with a tailored behavioral communication strategy an also equipped with smartphone-based tool linked to the AMRS. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Study population: Enrollment remains closed for this study. 2890 individuals (69.9% women) were enrolled (708 UC, 709 MF, 740 GMV, and 733 GMV-MF).
Site(s)	Nandi, Uasin Gishu
Project Period	4/1/2012 - 3/31/2022
Sponsor(s)	NHLBI; NYU Grossman School of Medicine
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	## Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Expand and modify an existing pediatric HIV disclosure intervention used in Kenya to include patient-centered components. Aim 2: Perform a randomized trial to compare the impact of clinic implementation of the culturally adapted, pediatric disclosure intervention on the prevalence of disclosure and on the medical, psychological and social outcomes for HIV-infected Kenyan children ages 10-15 years compared to children exposed to standard clinical care.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	1/9/2012 - 1/9/2016
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	Prevalence and Impact of SARS-CoV-2 Among Pregnant Women in Low- and Middle-income Countries
Principal Investigator(s)	Fabian Esamai (Moi University)
Collaborator(s)	Edward Liechty, Sherri Bucher (Indiana University), Irene Marete (Moi University), Constance Tenge (Moi University), Osayame Ekhaguere (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence of COVID-19 antibodies in pregnant/recently delivered women in 8 Global Network sites using antibody testing. Aim 2: To compare the maternal, fetal, and neonatal outcomes of COVID-19 antibody positive women vs. antibody negative women including low-birthweight, preterm birth, fetal growth restriction, stillbirth, and neonatal mortality. Aim 3: To assess knowledge, attitudes and practices of pregnant women related to COVID-19 and its prevention during pregnancy.
Site(s)	Bungoma, Busia, Kakamega
Project Period	11/15/2020 – ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. No updates provided for the current reporting period.

Study Title	Prevalence of hypertension among postpartum women with preeclampsia (PET) in Kenya: a prospective cohort study
Principal Investigator(s)	Gerald Bloomfield (Duke University)
Collaborator(s)	Felix Barasa (MTRH), Rebecca Lumsden (Duke University)
Study Type	Prospective
Specific Aim(s)	Aim1: To determine the prevalence of hypertension at 6 months postpartum among Kenyan mothers with preeclampsia. Sub-aim 1.1: To define the BP trajectory during the postpartum period among Kenyan mothers with preeclampsia. Aim 2: To identify risk factors associated with persistent hypertension among Kenyan mothers with preeclampsia. Aim 3: To characterize the acute cardiac structural and functional abnormalities among Kenyan mothers with preeclampsia. Aim 4: To explore post-delivery follow-up care for women with PET, including knowledge, location, barriers and rates of follow up
Site(s)	Moi Teaching and Referral Hospital

Project Period	1/6/2020 – ongoing
Sponsor(s)	NIH-FIC
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. We completed study follow-up and data collection as of May 31, 2021. We are now in the process of data cleaning and analysis and will be preparing for manuscript writing over the next 6 months. No updates provided for the current reporting period.
Study Title	Prevention of maternal and neonatal death/infections with a single oral dose of Azithromycin in women in labor (in low- and middle-income countries): a Randomized Controlled Trial (The A-PLUS study)
Principal Investigator(s)	Alan Tita (University of Alabama at Birmingham)
Collaborator(s)	Fabian Esamai (Moi University), Paul Nyongesa (Moi University), Ed Liechty (Indiana University), Sherri Bucher (Indiana University), Osayame Ekhaguere (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To test the effectiveness of a single dose of prophylactic intrapartum azithromycin compared to placebo in reducing the risk of the composite outcome of maternal death or sepsis. Aim 2: To separately test the effectiveness of a single oral dose of intrapartum azithromycin prophylaxis (2 g) compared to placebo in reducing the risk of the composite outcome of intrapartum/neonatal death or sepsis.
Site(s)	Bungoma, Busia, Kakamega
Project Period	10/30/2019 – ongoing
Sponsor(s)	NIH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. No updates provided for the current reporting period.
Study Title	Primary Health Integrated Care Project For Chronic Conditions In (PIC4C) Kenya: Pilot Project
Principal Investigator(s)	Jemima Kamano (Moi University)

Collaborator(s)	Thomas Andale (MTRH), Nicholas Kirui (MTRH), Imran Manji (MTRH). Ann Mwangi (Moi University), Peter Itsura (Moi University), Philip Tonui (Moi University), Kibet Keitany (MTRH), Violet Naanyu (Moi University)
Study Type	Prospective
Specific Aim(s)	1. Explore perceived barriers and facilitators to the prevention and management of select NCDs (Diabetes, hypertension, cancers of cervix and breast) at the primary health care level by; patients, community members and health providers in Busia and Trans Nzoia counties. 2. Describe the process of implementation of the integrated hypertension, diabetes, cervical cancer and breast cancer prevention and management model within primary health care setting in Trans Nzoia and Busia counties. 3. Evaluate the effectiveness of the integrated chronic care model for hypertension, diabetes, cervical and breast cancers within primary health care setting in Busia and Trans Nzoia counties of western Kenya. 4. Estimate the incremental cost and budget impact of scaling up the proposed project in Busia and Trans Nzoia counties of western Kenya.
Site(s)	Busia, Trans Nzoia
Project Period	8/1/2018 - 1/31/2022
Sponsor(s)	World Bank (Access Accelerated)
Status	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	Prospective study of Lopinavir based ART for HIV Infected children globally (LIVING study) 2
Principal Investigator(s)	Winstone Nyandiko (Moi University)
Collaborator(s)	Dalton Wamalwa (University of Nairobi), Samwel Ayaya (Moi University)
Study Type	Prospective
Specific Aim(s)	Primary objective: Evaluate the effectiveness of LPV/r pellets in addition to AZT/3TC (or ABC/3TC) paediatric fixed dose combination (FDCs) tablet under routine treatment conditions in HIV infected infants and young children who cannot swallow tablets. Secondary objectives: (1) Document the safety of LPV/r pellets and AZT/3TC or ABC/3TC; (2) Assess the population pharmacokinetics of LPV/r and NRTIs when administered as LPV/r pellets plus AZT/3TC or ABC/3TC; (3) Measure adherence to the new formulation; (4) Evaluate children acceptability of the LPV/r pellets and associated dual NRTIs as well as ease of use by the care giver.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/14/2016 – ongoing
Sponsor(s)	Drugs for Neglected Diseases initiative (DNDi)

Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	## PT4A (Peers and Technology for Adherence, Access, Accountability, and Analytics)
Principal Investigator(s)	Rajesh Vedanthan (New York University)
Collaborator(s)	Sonak Pastakia (Purdue University), Antoinette Schoenthaler (NYU), Andrea Troxel (NYU), Benson Njuguna (MTRH), Jeremiah Laktabai (MTRHl), Imran Manji (MTRH), Ann Mwangi (MTRH), Jonathan Dick (Indiana University), Dustin Duncan (Columbia), Tina Tran (Temple University), Becky Genberg (Johns Hopkins University)
Study Type	Prospective
Specific Aim(s)	The overall objective of this project is to utilize the PRECEDE-PROCEED framework to conduct transdisciplinary, translational implementation research focused on improving medication adherence for hypertension control. Aim 1: will identify micro- and macro-level contextual factors that might influence the implementation of the PT4A strategy (individual, family, clinician, health system, and environment), using qualitative methods. Aim 2: We will then use a human-centered design approach to refine the PT4A intervention using the findings from Aim 1. Sub-Aim 2.1: will evaluate the intervention for acceptability and appropriateness using focus group discussions with patients, peers, and clinical staff. In Sub-Aim 2.2: we will then conduct a pilot of the intervention and conduct focus group discussions with patients, peers, and clinical staff to evaluate feasibility. We will also evaluate impact on systolic blood pressure, medication adherence, and fidelity of implementation.
Site(s)	Bungoma, Trans Nzoia, Uasin Gishu
Project Period	9/25/2020 - 8/31/2021
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	## SAFI (Stigma in AIDS Family Inventory) Validation Study
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	WinstoneNyandiko (Moi University), Irene Marete (Moi University), Violet Nanyu (Moi University), Hai Liu (Indiana University)
Study Type	Prospective
Specific Aim(s)	The specific aims for the SAFI validation study were: Aim 1: Identify and modify HIV/AIDS stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized HIV/A stigma among Kenyan families with HIV-infected children. Aim 2: Assess the

	validity of the measures of perceived, enacted and internalized H/A stigma compared to independent construct measures including pediatric adherence to therapy and children's physical, psychological and social outcomes. Aim 3: Examine whether disclosure of a child's HIV status reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children.
Site(s)	Bungoma, Busia, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	12/17/2013 - 12/31/2015
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	Scaling Up Primary Health Integrated Care for Chronic Conditions in Kenya: An Implementation Research Project (PIC4C Scale Up Study)
Principal Investigator(s)	Pablo Perel (London School of Hygiene and Tropical Medicine)
Collaborator(s)	Jemima Kamano (Moi University), Edwine Barasa (Kenya Wellcome Trust Research Programme), Ellen Nolte (London School of Hygiene and Tropical Medicine), Gasparrini (London School of Hygiene and Tropical Medicine), Adrianna Murphy (London School of Hygiene and Tropical Medicine), Ruth Willis (London School of Hygiene and Tropical Medicine), Prof. Hanson (London School of Hygiene and Tropical Medicine), Anthony Etyang (Kenya Wellcome Trust Research Programme), Vincent Were (Kenya Wellcome Trust Research Programme), Violet Naanyu (Moi University), Nicholas Kirui (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	1) To understand the implementation process to assess the quality of leadership and management; levels of stakeholder involvement; adequacy of support mechanisms and resources; ability to adapt the intervention locally; and quality of communication and of monitoring and feedback; 2) To understand the experiences of patients to assess whether and how well the PIC4C model meets the needs of those affected by the selected NCDs; 3) To assess the health benefits (on hypertension, diabetes and cancer control) and potential unintended consequences (on HIV viral suppression) of the implementation of the PIC4C pilot 4) To evaluate the effectiveness of the NHIF chronic care benefit package to provide financial risk protection, to be responsive to the needs of individuals, to influence equity, efficiency, quality of care, and service delivery.
Site(s)	Busia, Trans Nzoia
Project Period	8/1/2020 – 8/31/2022
Sponsor(s)	UK Medical Research Council (MRC) through Global Alliance for Chronic Diseases

Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up. No updates provided for the current reporting period.

Study Title	Spatial scales of Plasmodium falciparum generations; implications for elimination
Principal Investigator(s)	Andrew Obala (Moi University)
Collaborator(s)	Wendy O'Meara (Duke University), Diana Menya (Moi University)
Study Type	Prospective cohort
Specific Aim(s)	The overall goal is to match infections in malaria-infected mosquitoes to malaria infections in humans in order to understand what persons infected each mosquito and the distance between the donor and the location where the mosquito was trapped. Aim 1: Measure the genetic relatedness of infections within the same household compared to the relatedness of infections at further distances to determine whether this relationship differs in fever 'hotspots' (geographic clusters of high fever incidence) and fever 'coldspots'. Aim 2: Trap malaria mosquito vectors and identify infected mosquitoes to determine the source of the mosquito's infection by sequencing parasites in the mosquito salivary glands and comparing to parasite genotypes in humans.
Site(s)	Bungoma
Project Period	7/1/2019 - 6/30/2021
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	Stated Preference Analysis to Refine PMTCT Service Delivery in Kenya (SPARK) study
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Edwin Were, Winstone Nyandiko, Violet Naanyu, Bett Kipchumba, Marsha Alera, Alan McGuire, Beverly Musick, James Carlucci, Constantin Yiannoutsos, Gregory Zimet, Kara Wools-Kaloustian
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1. Identify the relative importance of key PMTCT services according to PPHIV in western Kenya. Aim 2. Explore the influence of various characteristics of PPHIV on their preferences for different PMTCT services.
Site(s)	Busia, Moi Teaching and Referral Hospital, Uasin Gishu

Project Period	6/1/2021 – ongoing
Sponsor(s)	NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	Stawisha Jamii - Development of a Family-Level Problem Solving Intervention for Adolescents Living with HIV
Principal Investigator(s)	Leslie Enane (Indiana University)
Collaborator(s)	David Ayuku, Moi University Eve Puffer, Duke University Courtney Myers, Indiana University Edith Apondi, Moi Teaching and Referral Hospital Paula Braitstein, University of Toronto Kara Wools-Kalaoustian, Indiana University Rachel Vreeman, Mount Sinai University
Study Type	Prospective
Specific Aim(s)	Aim 1. Engage key stakeholders to determine the relevant needs and preferences for a family-level problem solving intervention (FPSI) for vulnerable ALHIV. Aim 2. Develop an FPSI for vulnerable ALHIV that is adaptable to address a range of barriers to care experienced at the family or household level. Aim 3. Pilot an FPSI to support HIV care for vulnerable ALHIV.
Site(s)	Bungoma, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	4/11/2022 – ongoing
Sponsor(s)	Unfunded
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)
Principal Investigator(s)	Constantine Olieba Akwanalo (Moi University)
Collaborator(s)	Jemima Kamano, Benson Njuguna, Violet Naanyu, Ann Mwangi, Timothy Mercer, Rajesh Vedanthan, Sonak Pastakia, Jonathan Dick, Makeda Williams
Study Type	Cluster randomized controlled trial
Specific Aim(s)	Aim 1: Evaluate the effectiveness of HIT and peer support on one-year change in SBP and CVD risk reduction. Aim 2: Conduct mediation analysis to evaluate the influence of changes in referral network characteristics on intervention outcomes, and a moderation analysis to evaluate the influence of baseline referral network characteristics on the effectiveness of the intervention. Aim 3: Conduct a process evaluation using the Saunders framework, evaluating key implementation

	measures related to fidelity, dose delivered, dose received, recruitment, reach, and context. Aim 4: Evaluate the incremental cost-effectiveness of the intervention, in terms of costs per unit decrease in SBP, per percent change in CVD risk score, and per DALY saved.
Site(s)	Bungoma, Busia, Nandi, Trans Nzoia, Uasin Gishu
Project Period	9/1/2017 - 5/31/2022
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	Subclinical Cardiac Dysfunction in Children and Adolescents with and without HIV
Principal Investigator(s)	Gerald Bloomfield (Duke University)
Collaborator(s)	Winstone Nyandiko (Moi), Myra Maghasi Koech, (MTRH), Andrew McCrary (Duke), Piers Barker (Duke), Svati Shah (Duke), Nathan Thielman (Duke)
Study Type	Prospective
Specific Aim(s)	To determine if advanced echocardiographic measures of cardiac function can detect early stages of cardiomyopathy in CALHIV and if the burden of subclinical changes on echocardiography is dissimilar from HEU and HU children.
Site(s)	Uasin Gishu (MTRH)
Project Period	9/21/2021 - 12/31/2022
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	The East Africa Consortium for HPV and Cervical Cancer in Women living with HIV/AIDS
Principal Investigator(s)	Patrick Loehrer (Indiana University)
Collaborator(s)	Darron Brown - IU Miriam Nakalembe - Makerere University Omenge Orang'o - MTRH Jeff Bailey - Brown Susan Cu-Uvin - Brown Aaron Ermel - IU Peter Itsura - MTRH Rachel Katzenellenbogen - IU Agnes Kiragga - Makerere University Robert Lukande - Makerere University Ann Moormann - UMass Bev Musick - IU Ann Mwangi - MTRH Damalie Nakanjako - Makerere University Elly Odongo - MTRH

	Kirtika Patel - MTRH Barry Rosen - Beaumont Health Yan Tong - IU Philip Tonui - MTRH Ronald Tonui - MTRH Constantin Yiannoutsos - IU Benson Macharia - MTRH
Study Type	Prospective
Specific Aim(s)	The specific aims for the East Africa Consortium for HPV and Cervical Cancer (EACHC) in Women Living with HIV/AIDS are: Specific Aim 1. To establish a sustainable research infrastructure for an international partnership to conduct impactful research in HPV and cervical cancer in women living with HIV/AIDS Specific Aim 2. To design and execute three integrated projects that advance the knowledge of the environmental and biologic factors leading to cervical cancer in East Africa: Project 1- Preventing cervical cancer in HIV-infected women Project 2- Understanding CIN2+ among HIV infected women after LEEP: An epidemiological and immunohistochemical study Project 3- Determining biological and viral factors associated with clinical progression of cervical dysplasia in HIV-infected women Specific Aim 3. To increase the research workforce capacity in East Africa through mentoring, training programs and targeted pilot projects
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Uasin Gishu, Kampala (Uganda)
Project Period	9/7/2020 - 8/31/2025
Sponsor(s)	NIH-NCI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	The Effect of Weekly Text Messaging to Improve Retention across the PMTCT Cascade for Pregnant HIV- infected Women: Study Protocol for a Randomized Controlled Trial (WelTel PMTCT)
Principal Investigator(s)	Anna Mia Ekström (Karolinska Institutet)
Collaborator(s)	Edwin Were (Moi University)
Study Type	Prospective
Specific Aim(s)	The primary objective is to determine the effectiveness of the WelTel SMS intervention on retention of women living with HIV and their newborns in PMTCT care in urban and rural Kenya. Secondary Objectives 1: To assess adherence to the WelTel SMS intervention among pregnant women and newly delivered mothers living with HIV. Objective 2: To determine adherence to single components of PMTCT among pregnant women and newly delivered mothers living with HIV (ARVs, facility-based delivery, early infant HIV testing, and exclusive breastfeeding). Objective 3: To explore facilitators for and barriers to using WelTel SMS in order to inform any improvements on the model for PMTCT among pregnant women and newly delivered mothers living with HIV as well as PMTCT staff. Objective 4: To evaluate costs from a payer's perspective, of the WelTel SMS for retaining women living with HIV and HIV-exposed infants in clinical follow-up until 24 months post-delivery (discharge from PMTCT).

Site(s)	Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/25/2015 – ongoing
Sponsor(s)	Swedish Research Council
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	The Impact of Using Hemotype SCTM in Screening for Sickle Cell Disease in Neonates, Infants, and Children under Five Years of Age in a Resource-Limited Setting
Principal Investigator(s)	Christopher Mwaniki (Duke University)
Collaborator(s)	Festus Njuguna (Moi University), Ann Greist (Indiana Hemophilia and Thrombosis Centre), Chris Roberson (Indiana Hemophilia and Thrombosis Centre)
Study Type	Prospective
Specific Aim(s)	Aim 1: To evaluate the uptake of HSST among immunization population. Aim 2: To evaluate the proportion of those screened with HSST and get followed up through the Hb Electrophoresis. Aim 3: To determine the rate of enrollment of those found to have sickle cell into the comprehensive sickle cell clinic. Aim 4: To evaluate the prevalence of sickle cell among screened children age 5 and below presenting in the immunization clinic at the Homabay county referral hospital.
Site(s)	Homabay County Referral Hospital
Project Period	12/1/2020 - 12/1/2022
Sponsor(s)	None
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	The Prevalence of and Risk Factors for Non-Alcoholic Fatty Liver Disease in Kenya
Principal Investigator(s)	Fatuma Some (Moi University)
Collaborator(s)	Naga Chalasani, Niharika Samala, Suzanne Goodrich, Mercy Karoney, Alexa Monroy
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence of steatosis and hepatic fibrosis in PLHIV and in individuals without HIV infection where diagnosis is based on predefined clinical, laboratory, and imaging

	criteria. Aim 2: To develop a bio-specimen bank comprised of serum, plasma, and DNA obtained from PLHIV and in individuals without HIV infection to support the evaluation the independent effects of ART, HIV factors, gene variants, and metabolic abnormalities on risk of fatty liver.
Site(s)	Moi Teaching and Referral Hospital
Project Period	3/1/2021 – 7/31/2022
Sponsor(s)	Indiana University
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposo Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya
Principal Investigator(s)	Patrick Loehrer (Indiana University)
Collaborator(s)	Toby Maurer, MD (Indiana University), Chite Asirwas (International Cancer Institute)
Study Type	Prospective
Specific Aim(s)	To look for the PD-1 pathway in Kaposis sarcoma (KS) tissue from an HIV cohort and endmic cohort
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2015-8/31/2019
Sponsor(s)	NCI supplemental grant
Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	Virologic Treatment Failure and Drug Resistance in HIV-infected Kenyan Children
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Rami Kantor (Brown University), Samuel Ayaya (Moi University), Joe Hogan (Brown University)
Study Type	Prospective cohort (with additional retrospective analyses)
Specific Aim(s)	Aim 1: Determine prevalence of viral failure and examine resistance mutations among a retrospective study cohort of 685 prenatally HIV-infected Kenyan children on 1st-line ART. Aim 2: Investigate associations between specific adherence patterns, ART drug levels and other

	demographic and clinical factors, with viral failure and drug resistance. Aim 3: Study long-term immunologic, virologic and drug resistance outcomes and their associations in prospectively re-enrolled study participants Aim 4: Enhance analyses of viral failure, drug resistance accumulation and associated demographic and clinical factors by examining the longitudinal banked samples available for a subset of the study cohort (n=327). Aim 5: Develop a data-driven intervention algorithm to identify children at risk for viral failure and resistance.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/2/2017 - 7/31/2020
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	## World Bleeding Disorders Registry (WBDR)
Principal Investigator(s)	Festus Njuguna (Moi University)
Collaborator(s)	Donna Coffin (World Federation of Hemophilia), Glenn Pierce (World Federation of Hemophilia), Alain Baumann (World Federation of Hemophilia)
Study Type	Prospective
Specific Aim(s)	WBDR will aim to address the following: Aim 1: Identify gaps in evidence related to diagnosis, access to care, treatment, and outcomes in patients that include: • Comparative evaluation of preventative treatment regimens (e.g., prophylaxis) • Identification of high-risk populations • Inhibitors and other complications of BD • Trends in treatment patterns over time • Discrepancies in quality of care • Data on factor utilization. Aim 2: Collection of data to support advocacy initiatives aimed at improving diagnosis and access to care around the world, such as: • Burden of disease data: • Annual bleeding rate • Functional assessment • Hospitalization • Lost days of school/work • Educational/employment attainment • Between country discrepancies in factor usage.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/6/2018 – ongoing
Sponsor(s)	None
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.