2020-2021

ANNUAL REPORT

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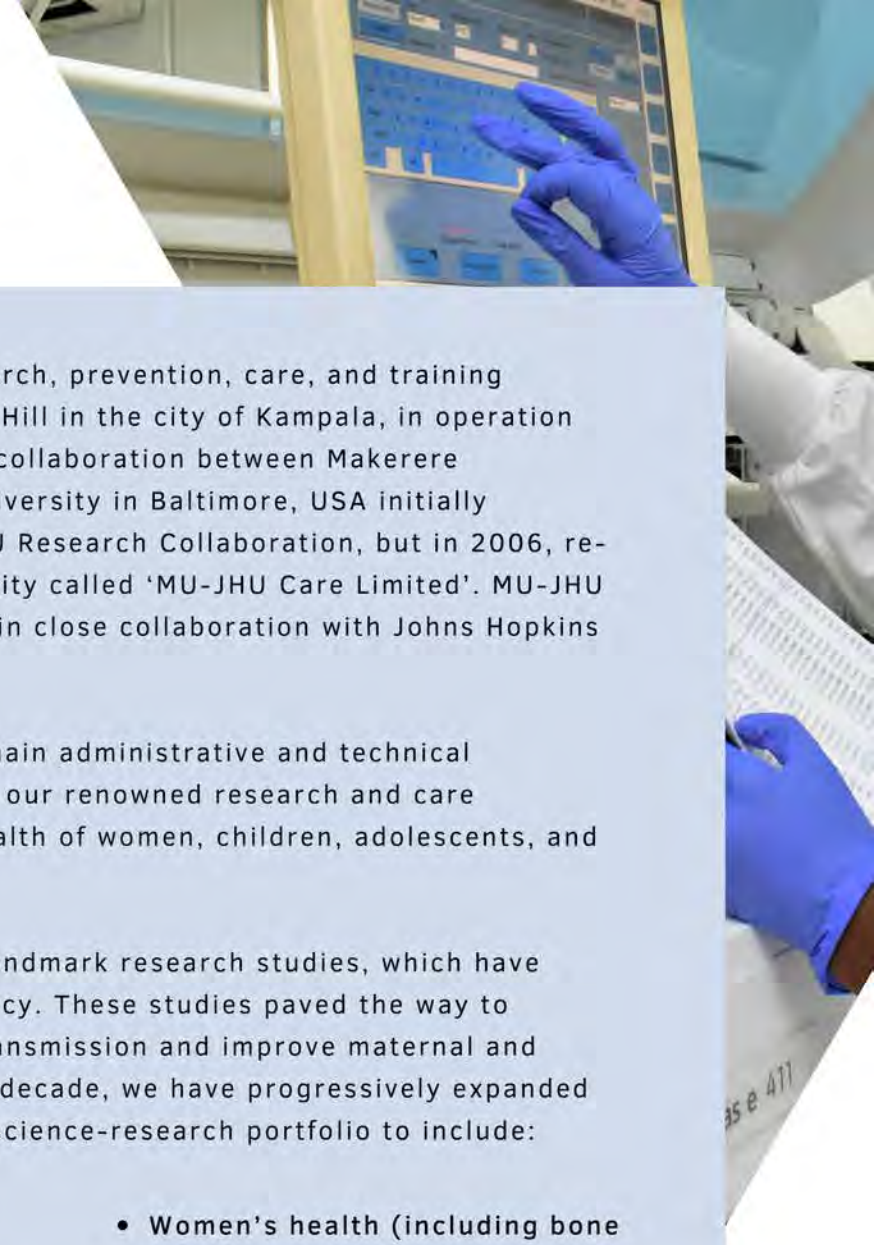
MU-JHU CARE LTD
MU-JHU RESEARCH COLLABORATION

about

MU-JHU



MU-JHU Care LTD is an HIV research, prevention, care, and training facility located on Upper Mulago Hill in the city of Kampala, in operation since 1988. MU-JHU embodies a collaboration between Makerere University and Johns Hopkins University in Baltimore, USA initially operated under the name MU-JHU Research Collaboration, but in 2006, re-registered as a not-for-profit entity called 'MU-JHU Care Limited'. MU-JHU remains a Clinical Research Site in close collaboration with Johns Hopkins University.

Our Mulago campus houses the main administrative and technical structures from where we launch our renowned research and care activities. Our focus is on the health of women, children, adolescents, and their families.

MU-JHU has conducted several landmark research studies, which have informed global and national policy. These studies paved the way to eliminate mother-to-child HIV transmission and improve maternal and pediatric HIV care. Over the last decade, we have progressively expanded our clinical and implementation science-research portfolio to include:

- Primary HIV prevention
- Tuberculosis diagnosis and management
- Paediatric neurodevelopment assessment and interventions
- Birth-defects surveillance
- Women's health (including bone health and reproductive health)
- The development of a maternal vaccine platform to assess Group-B Streptococcus and other promising vaccines

VISION

A centre of excellence in clinical research, provision of care- related capacity building which has a positive impact on the health of children, women and their families.

MISSION

To improve the health state of families infected and affected by HIV/AIDS through research, training, prevention and care.

MU-JHU

AT A GLANCE

62
Active Studies

Over
21
Study publications

396
Staff

Co-organised a global virtual symposium on Community and Youth in science-led HIV response in EA with IAS

Hosted the 2021 Annual PROMOTE Network Meeting

436
YGA members

a year's overview

WHERE WE ARE NOW

The Makerere University-Johns Hopkins University Research Collaboration (MU-JHU) continues to do high-impact research for women, children, youth, and families, as well as provide comprehensive HIV care and treatment.

During 2020–2021, MU-JHU conducted multiple HIV prevention and treatment clinical trials, and maternal and child health research. In addition, MU-JHU also implemented the HIV care and treatment program in partnership with Kawempe National Referral Hospital. Despite the COVID-19 pandemic, MU-JHU successfully retained study participants in clinical trials and provided ongoing treatment for clients enrolled in the HIV care program. The staff worked very hard during this difficult time and were supported by MU-JHU to remain safe and navigate the lock-downs.

Critical trial results:

1. HPTN-084 Long-acting injectable Cabotegravir was shown to significantly reduce HIV acquisition in high-risk women and was superior to oral Truvada.
2. SHINE trial demonstrated that TB treatment for 4 months in children with non-severe tuberculosis was not inferior to the standard 6 months.

We look forward to continuing our work in highly relevant research, to improve the lives of people living in Uganda and beyond.

Dr. Samuel Okware
Board Chairperson
MU-JHU Care Ltd

Prof. Philippa Musoke
Executive Director
MU-JHU Care Ltd

Table of Contents

	I	Our Board of Directors
	II	Our Senior Management Team
01 Research & Programs	Page 01- 05	Clinic Division
	Page 06- 09	Psychosocial Support Division
02 Operations	Page 10	Quality Management Division
	Page 11	Human Resource Division
	Page 12 -13	Grants & Partnerships
	Page 14- 16	Regulatory Affairs Coordination
03 Finance	Page 17-19	Financial Performance Report
	Page 20	Pictorial: Milestones
	Page 21	Acknowledgements
	Page 22	Annex I: List of MU-JHU Studies
	Page 23	Annex II: List of Abbreviations & Acronyms
	Page 24	Annex III: Financial Statements 30 June 2021

Our

BOARD OF DIRECTORS

Dr. Samuel Okware (MBCHB, MPH, PhD)
Chairperson

Prof. Brooks Jackson (MD, MBA)
Vice-Chairperson

Prof. Mary Glenn Fowler (MD MPH)

Prof. Christopher M. Ndugwa (MBChB, MMed Paed, DCH,DTM&H)

Dr. Richard Brough (BA, MSc, PhD, FFPH)

Dr. Diana Atwine Kanzira (MBChB, MMed)

Prof. Nelson Sewankambo (M.B.CH.B, M.MED, M.SC clinical epidemiology)

Mr. David Nuwamanya BASS, MPA (MUK)

Alex M. B. Twesigye BSC, MBA, ACCA /CPA (U), CIA, CGAP, CISA

Our

SENIOR MANAGEMENT TEAM

Prof. Philippa Musoke
MBCHB,PhD FAAP
Executive Director

Dr. Clemensia Nakabiito
MBCHB,MMed (Obs/Gyn)
Clinical Site Leader

Juliane Etima
Director
Psychosocial
Support

Dr. Lillian Wambuzi
Director
Clinic

Airene Profeta Dasal
Director
Administration &
Finance

Dr. Agnes M. Mugaga
Director
Quality
Management

Jane Ndamata
Director
Human Resource

Denis Akakimpa
Director
Strategic Planning
and Partnerships

Chapter 1:

RESEARCH & PROGRAMS

A. Clinic Division

The Clinic Division runs the fundamental research and client-care business of the MU-JHU Institution. The division's mandate is to conduct high-quality HIV and non-HIV clinical research as well as to provide excellent holistic care in paediatric, adolescent and adult HIV populations.

In the Research section, we undertake investigatory studies on new drugs and medical interventions. Our Programs section constitutes of the Comprehensive HIV Prevention, Care and Treatment Program. The clinic runs activities at MU-JHU (located on Mulago Hill) and at collaborative sites which include the Mulago National Referral Hospital, Kawempe National Referral Hospital, St. Francis Hospital Nsambya, Uganda Martyrs Hospital Lubaga and Mityana District Hospital.

In the year 2020, the division was able to conduct a total of 12 HIV research studies and 11 non-HIV studies in the areas of Birth Defects Surveillance; Neurodevelopment; Bone Health; TB disease prevention and treatment; treatment and prevention technologies and vaccine studies (See Annex 1).

Study nurses review paperwork at the MU-JHU 2 client checkout desk

Henry Makoka, Lab technologist- Stat Lab

Nurse Nassoma in the newly renovated Dispensary room in the MU-JHU 1 building.

The Family Care Clinic was able to provide services to over 3000 clients including; ARV treatment, counselling and prevention of mother-to-child transmission of the disease to newborn infants.

A pause in clinical activities occurred on 30 Mar 2020 but work resumed in July 2020 after the lifting of the nationwide lock-down. In spite of the devastating COVID-19 pandemic, we had achievement in 2020. This included continuity of critical research activities and HIV care. Less than 5% of HIV infected clients missed their medications due to failed access to the facility. Clinical staff took on new pragmatic approaches to ensure drug delivery for clients. The clinic division also successfully spearheaded COVID-19 infection prevention at the workplace resulting in only one confirmed diagnosis by the end of 2020.In the same year, MU-JHU readily embraced research opportunities in COVID-19 research, culminating into two large ongoing vaccine trials, among other studies.

Other research highlights in 2020 were growth in local investigator-led clinical research in the areas of bone health and ARV drug adherence. There was also expansion in adolescent health research protocols. The division also strengthened workplace safety through rigorous COVID-19 prevention guidance, TB infection control and HIV workplace policies.

In the year 2021, the majority of studies were ongoing from 2020. New studies were in the area of Neurodevelopment.

Workplace safety remained key and our success story here was that out of 396 MU-JHU staff members only 14 were confirmed to have had COVID-19 and there were no moralities or major complications post COVID-19. No infections were diagnosed among our research participants.

With the gradual recovery from the COVID -19 lockdown, later 2021 had a re-focus on professional growth.

In April 2021, one of the vibrant doctors in adolescent studies, Dr. Brenda Gati was selected as a voting member of the HPTN **Adolescent Science Committee.** The goal of this committee is to develop and review concepts for HIV prevention science for adolescents and young people by providing guidance and input on HPTN research.

One key achievement of 2021 was the completion of the major Pharmacy refurbishment which begun 2020. The MU-JHU pharmacy underwent a major transformation, from a space that previously served fewer studies to a larger, more complex unit. The space currently serves bigger study numbers and performs more complex processes such as vaccine study product-preparation at Internationally-acceptable levels. The completed works were visited by the Chairman of the MU-JHU Board of Directors Dr. Samuel Okware and the then acting, Executive Director of Mulago National Referral Hospital, Dr. Rosemary Byanyima.

The contractor responds to questions from the finance and clinic team regarding Pharmacy renovations.

The COVID Research Centre in May 2021

Articles published between July 2020- June 2021

Study	Paper	Journal	Authors
SEARCH UTT trial	Population-level viral suppression among pregnant and postpartum women in a universal test and treat trial. **Published 15 July 2020** **DOI: 10.1097/QAD.0000000000002564**	AIDS	Kabami, Janea; Balzer, Laura B.; Saddiki, Hachem; A et al
Option B+	PMTCT Option B+ 2012 to 2018 - Taking stock: barriers and strategies to improve adherence to Option B+ in urban and rural Uganda **Published 19 July 2020** **doi: 10.2989/16085906.2020.1760325**	African Journal of AIDS Research	Rachel King, Joyce Namale Matovu, Joseph Rujumba et al
Non-uptake of viral load testing among people receiving HIV treatment in Gomba district	Non-uptake of viral load testing among people receiving HIV treatment in Gomba district, rural Uganda **Published online 6 October 2020** **https://doi.org/10.1186/s12879-020-05461-1**	BMC	Nakalega, R., Mukiza, N., Kiwanuka, G., Makanga-Kakumba, R., Menge, et al
BONE: CARE (Contraception and Anti-Retroviral Effects)	Bone Mineral Density in Antiretroviral Therapy- Naive HIV-1-Infected Young Adult- Women Using Depot Medroxyprogesterone Acetate or Non-hormonal Contraceptives in Uganda **Published 7 December 2020** **DOI: 10.1002/jbm4.10446**	JBMR Plus	Flavia Kiweewa Matovu, Martin Nabwana, Noah Kiwanuka, et al
PROGRESS GBS	Seroepidemiology of maternally-derived antibody against Group B Streptococcus (GBS) in Mulago/Kawempe Hospitals Uganda - PROGRESS GBS **Published 13 November 2020** **doi: 10.12688/gatesopenres.13183.2.** **eCollection 2020**	Gates Open Research	Mary Kyohere, Hannah Georgia Davies, Philippa Musoke et al
MTN-020/ASPIRE	Greater dapivirine release from the dapivirine vaginal ring is correlated with lower risk of HIV-1 acquisition: a secondary analysis from a randomized, placebo-controlled trial **First published: 18 November 2020** **https://doi.org/10.1002/jia2.25634**	Journal of the Internal AIDS Society	Elizabeth R Brown, Craig W Hendrix Ariane van der Straten et al

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Study	Paper	Journal	Authors
IMPAACT P1092	Pharmacokinetics and Safety of Zidovudine, Lamivudine and Lopinavir/Ritonavir in HIV-Infected Children with Severe Acute Malnutrition in Sub-saharan Africa:IMPAACT Protocol P1092 **Accepted for publication 19 December 2020** **DOI:10.1097/INF.0000000000003055**	The Pediatric Infectious Disease Journal	Maxensia Owor , Camlin Tierney, Lauren Ziemba, Renee Browning , et al
AFREhealth COVID-19 Research Collaboration Working Group	Effect of SARS-CoV-2 Infection in Pregnancy on Maternal and Neonatal Outcomes in Africa: An AFREhealth Call for Evidence through Multicountry Research Collaboration **Published 28 December 2020** **DOI: 10.4269/ajtmh.20-1553**	The American Journal of Tropical Medicine and Hygiene	Jean B. Nachega, Nadia A. Sam-Agudu, Samantha Budhram et al
Time to first viral load testing among pregnant women living with HIV initiated on option B+ at 5 government clinics in Kampala city, Uganda: Retrospective cohort study	Time to first viral load testing among pregnant women living with HIV initiated on option B+ at 5 government clinics in Kampala city, Uganda- retrospective cohort study. Published **Accepted 4 January 2021** **doi: https://doi.org/10.1016/j.ijid.2021.01.005**	International Journal for Infectious Diseases	Patience Atuhaire, Flavia Matovu, Rita Nakalegaa, et al
ODYSSEY Trial	ODYSSEY clinical trial design: a randomised global study to evaluate the efficacy and safety of dolutegravir-based antiretroviral therapy in HIV-positive children, with nested pharmacokinetic sub-studies to evaluate pragmatic WHO-weight-band based dolutegravir dosing. **Published 4 January 2021** https://doi.org/10.1186/s12879-020-05672-6	BMC Infect Diseases	Cecilia L. Moore, Anna Turkova, Hilda Mujuru, et al
Option B+	Loss to follow up after pregnancy among mothers enrolled on the option B+ program in Uganda **Available online 26 January 2021** **https://doi.org/10.1016/j.puhip.2021.100085**	Public Health Practice 2	Yerusa Kiiryaa, Philippa Musoke, Gloria Adobea Odei Obeng-Amoakoa et al
Low bone mass in people living with HIV on long-term anti-retroviral therapy	Low bone mass in people living with HIV on long-term anti-retroviral therapy: A single center study in Uganda. **Published: 5 February 5 2021** **https://doi.org/10.1371/journal.pone.0246389**	PLOS ONE	Erisa Sabakaki Mwaka , Ian Guyton Munabi, Barbara Castelnuovo, et al

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Study	Paper	Journal	Authors
Birth Defects Surveillance	Comparative Analysis of perinatal outcomes and birth defects amongst adolescent and older Ugandan mothers: evidence from a hospital-based surveillance database **Published 4 March 2021** **https://doi.org/10.1186/s12978-021-01115-w**	BMC	Robert Serunjogi, Linda Barlow-Mosha, Daniel Mumpe-Mwanja, et al
Virologic response of treatment experienced HIV-infected Ugandan children and adolescents on NNRTI based first-line regimen, previously monitored without viral load	Virologic response of treatment experienced HIV-infected Ugandan children and adolescents on NNRTI based first-line regimen, previously monitored without viral load **Published 22 March 2021** **https://doi.org/10.1186/s12887-021-02608-0**	BMC Pediatrics	Phionah Kibalama Ssemambo, Mary Gorrethy Nalubega-Mboowa, Arthur Owora, et al
MTN-020/ASPIRE Study	Experiences with simultaneous use of contraception and the vaginal ring for HIV prevention in sub-Saharan Africa **Published: 23 April 2021** **https://doi.org/10.1186/s12905-021-01321-5**	BMC Women's Health	Jonah Leslie, Flavia Kiweewa, Thesla Palanee-Phillips, et al
Time to first viral load testing among pregnant women living with HIV initiated on option B+ at 5 government clinics in Kampala city, Uganda: Retrospective cohort study	Time to first viral load testing among pregnant women living with HIV initiated on option B+ at 5 government clinics in Kampala city, Uganda- retrospective cohort study. Published **Accepted 4 January 2021** **doi:** **https://doi.org/10.1016/j.ijid.2021.01.005**	International Journal for Infectious Diseases	Patience Atuhaire, Flavia Matovu, Rita Nakalegaa, et al
Birth Defects Surveillance	Comparative Analysis of perinatal outcomes and birth defects amongst adolescent and older Ugandan mothers: evidence from a hospital-based surveillance database **Published 4 March 2021** **https://doi.org/10.1186/s12978-021-01115-w**	BMC	Robert Serunjogi, Linda Barlow-Mosha, Daniel Mumpe-Mwanja, et al

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Study	Paper	Journal	Authors
Predictors of Failure on Second-line Antiretroviral Therapy with Protease Inhibitor Mutations in Uganda.	Predictors of Failure on Second-line Antiretroviral Therapy with Protease Inhibitor Mutations in Uganda. **Published: 21 April 2021 https://doi.org/10.1186/s12981-021-00338-y**	AIDS Research and Therapy	Hellen Musana, Jude Thaddeus Ssensamba, Mary Nakafeero et al
MTN-020/ASPIRE Study	Experiences with simultaneous use of contraception and the vaginal ring for HIV prevention in sub-Saharan Africa **Published: 23 April 2021 https://doi.org/10.1186/s12905-021-01321-5**	BMC Women's Health	Jonah Leslie, Flavia Kiweewa, Thesla Palanee-Phillips, et al
MTN-020/ASPIRE	Correlates of Adherence to the Dapivirine Vaginal Ring for HIV-1 Prevention **Published: 11 June 2021**	AIDS and Behavior	Marla J. Husnik, Elizabeth R. Brown, Sufia S. Dadabhai et al
Modifiers of Tenofovir in the Female Genital Tract	Depot medroxyprogesterone acetate and the vaginal microbiome as modifiers of tenofovir diphosphate and lamivudine triphosphate concentrations in the female genital tract of Ugandan women: implications for tenofovir disoproxil fumarate/lamivudine in preexposure prophylaxis **Published 10 April 2021 doi: 10.1093/cid/ciz443.**	Clinical Infectious Diseases	Melanie R. Nicol, Prosperity Eneh , Rita Nakalega et al

B. Psychosocial Support Division

The Psychosocial Support (PSS) division seeks to expand the behavioural research portfolio, strengthen community engagement, and provide psychosocial support to children, women, and families. The PSS team's focus in 2020/21 was to improve the research experience of participants by providing competent mental and social services.

We re-engaged communities and stakeholders who had been impacted by the global COVID-19 pandemic. During the COVID-19 pandemic, the PSS team was also critical in supporting the psychological well-being of MU-JHU staff. Individual and group counselling sessions were provided by PSS team psychologists, who used Talk Therapy, motivational interviewing, and active follow-up. This assisted in reducing anxiety, developing coping skills, relieving fears, and re-energising staff to perform during this extremely stressful period.

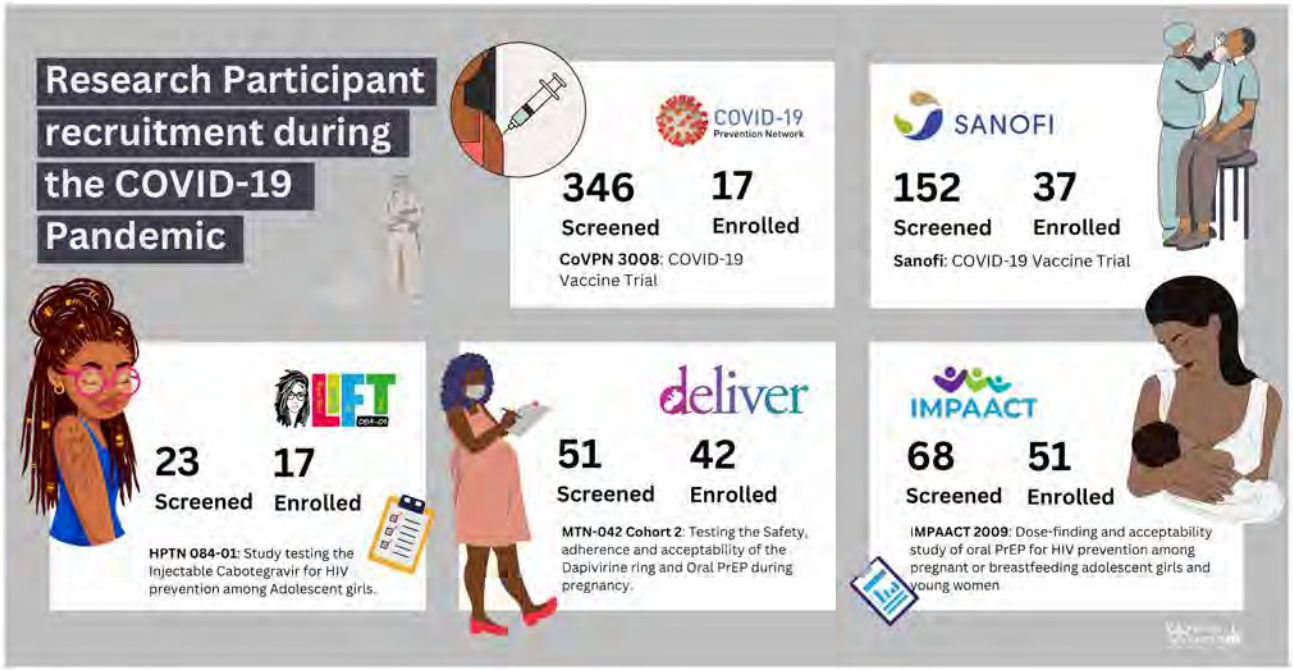
PSS teams carried out a number of activities that resulted in positive outcomes to support research studies and programs.

The community team re-planned, resulting in new ways of engaging communities and key stakeholders. This was critical because large group meetings were no longer viable or safe.

In collaboration with the Community Advisory Board(CAB) and Community Contact Persons, our community section undertook science-research education of the community. With this firmly in place, the team went on to;

- Prepare participants for study recruitment
- Obtain community feedback
- Facilitate community activities for on-going studies
- Coordinate dissemination meetings

In the period 2020-2021, this section's greatest achievement was its ability to recruit participants despite the reduced physical contact with the community because of the COVID-19 pandemic restrictions. This was achieved through increased community contact person's engagement.



MU-JHU prides itself in practicing ethical research. In order to ensure, the Counselors play their part by obtaining informed consent from participants, giving information, providing emotional support, and social help to study participants. Our counsellors are also responsible for supporting research participants to adhere to the study/program's product, guidelines and rules as well as its activities and requirements.

The achievements for the counsellors in this period include;

- Screening/enrollment consenting with no violations for the CoVPN, SANOFI, IMPAACT 2017, IMPAACT 2009, MTN-042 (cohort 2), CD PROMOTE, PROMOTA, Maternal Bone Care studies.
- Certification of 4 out of 7 counsellors to provide integrated next step counseling (iNSC) for IMPAACT 2009.
- Building the capacity of counsellors to provide client-centered counselling for MTN-042 with MU-JHU counsellors being among the best-rated counsellors scoring an average of 4.5 on a scale of 1-5 (1 being the lowest and 5 the highest), with 3 counsellors.
- The **vicarious trauma** and **burn-out** sessions completed for all the 32 counsellors.

In order to contribute meaningful results for any research study/program, it is imperative to maintain high retention rates throughout the research/program lifespan. The Health visitor played the primary function of client retention in MU-JHU research studies and programs, while improving the client experience. The average retention rate across MU-JHU studies was 90%, which is a significant accomplishment considering COVID-19 pandemic restriction that limited movement of participants to the clinic. Some of the research participants were also forced to move to their rural homes due to COVID-19's the socio-economic impact on their livelihoods.

The most difficult challenge was/is the failure to follow up on HPTN participants who were relocated to Middle Eastern countries for work.

To support the recruitment and retention efforts of the PSS team are the Peer Educators, who have a unique lived experience willingly share with research/program participants. the played a major role in the adherence and retention rates that we are seeing above. The Peer Educators support the Informed consent process to ensure that it is free of coercion. They also support participants to deal with difficult diagnoses like HIV infection by sharing their life experiences/testimonies.

To complete the goal of offering Psychosocial support to children, women and their families, the PSS team evocatively engaged children adolescents' and youth with the aim of improving the well-being of children, adolescents and youth living and affected by HIV/AIDS.

average participant retention rate across MU-JHU studies

Due to the restrictions of the COVID-19 pandemic, digital solutions were developed to reach young people living with HIV/AIDS ensuring they received the support they required (psychosocial support, medication). This innovation enabled us continue to provide services to children, adolescents and youth growing their number to 436 in 2020/2021.

Additionally we were able to empower the adolescent and youth with skills for economic development. The imparted skills included; tailoring (25 youth) and face-mask making (15 youth).

The trained youth extended the skills they acquired to adolescents in two of MU-JHU's adolescent studies, HPTN 084-01and MTN-034. These included Hairdressing (32),tailoring (25), cosmetology (7), snack preparation (19). With funding from Stephen Lewis Foundation (SLF) we were able to offer food parcels to children, adolescents and youth during the COVID-19 pandemic. Majority of the children, adolescents and youth (98%) are in school and the pregnancy rate remains low at 2%.

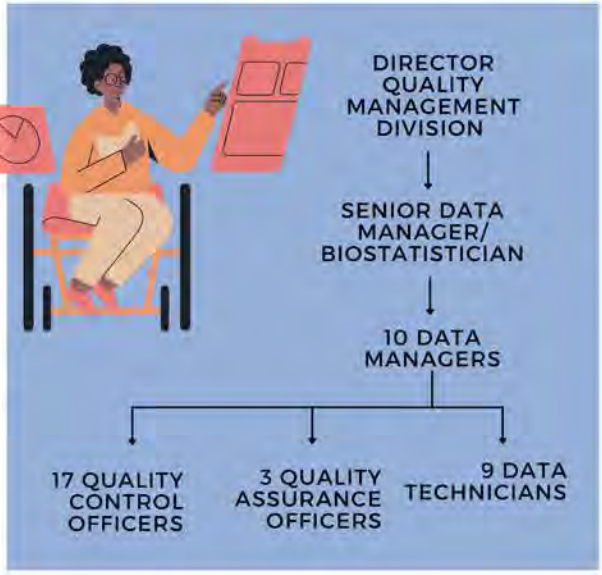
Growing the Behavioral research remains our mandate therefore the team supported the development and implementation of eight (8) [MTN-045, MTN-034, MTN-042, MTN-043, HPTN 084-01, HPTN 084-02, PROMOTA and PeerD] qualitative studies focusing on understanding participants' acceptability of and adherence to HIV prevention products like; long acting injectable Cabotagravir, Vaginal Dapivirine Ring and oral PrEP and use of Peers to support PrEP delivery. The team set high standards of qualitative data thus putting the sight in a favorable position for selection to conduct qualitative studies.Two team member has authored papers as a primary authors and the team has been co-authors on over 20 papers.

MU-JHU Peer Educator teaching sewing

MU-JHU Peer Educator teaching hairdressing

Cosmetology training on makeup application

Catering training on snack preparation



Chapter 2

OPERATIONS

A. Quality Management Division

The Quality Management Division, under the supervision of the Division Director, is responsible for the data and research quality of the organization. The teams that make up the Division include the Quality Control, Quality Assurance, and Data staff whose education backgrounds vary from medicine, nursing, statistics, epidemiology, and data management. The Quality Control and Quality Assurance services ensure that the institution's research operations and data adhere to the approved study protocol as well as to the ethical and sponsor requirements, guaranteeing participant safety and data integrity. This is ensured through meticulous quality resource and activity planning, and the predetermination of quality metrics, which are documented in the institution's leadership-approved quality management plan to guide the implementation of quality research.

In 2020 - 2021, the division had one division director,19 Quality control staff, 2 quality assurance officers, one senior data manager/biostatistician, 10 data managers, and 9 data technicians. Other quality tools include Standard Operating Procedures (SOPs), such as Quality Control and Quality Assurance SOPs, and manuals for data management. The data team supports data management operations including designing data collection instruments, randomization, data entry of participant data obtained from paper documents, quality evaluation, and error/query resolution of electronically captured participant data for both clinical trials and observational studies. They also support data analysis and protocol development. The team has managed research data on numerous secure commercially available electronic data systems such as Medidata's Rave EDC system, REDCap, OpenClinica, Cactus, ODK, and iDataFax.

Our Data Centre in MU-JHU 2

B. Human Resource Division

Human capital is one of our highest priorities, and our goal is to recruit, develop, manage and retain the best talent. During the period 2020-2021, 396 full-time and part-time employees supported the research and program portfolios of the organization. The employee retention rate was over 90%, primarily owing to the careful staffing plans, and the support offered to our staff even amidst the challenges of the COVID-19 lockdown. During the period, 76 new personnel were also welcome additions to the different teams.

We have a wide variety of range of professionals in clinical research and management, and it is this diversity that has allowed MU-JHU to contribute significantly to the national and international research agenda. We want to continue providing a conducive environment for our teams so that they can continue to contribute to ground-breaking research that promotes the health of women, children and youth of Uganda and the world. The Human Resourse division continues to serve as a broad resource for the majority of our workers' daily queries, circumstances, and needs.

The year 2020 marked the beginning of the COVID-19 pandemic and management's primary concern was the health and safety of our personnel. In order to avoid the transmission of the coronavirus, we implemented a shift system in which only essential staff were transported to work sites with support from the Ministry of Health that granted them permission to move through the lock-down period. At the workplace, strict COVID-19 preventive measures were implemented. A remote work model for non-essential workers and other teams that could operate from home, with email and videoconferencing replacing most of the face-to-face communication that would have been hard to implement within the COVID-19 measures.

In addition, the organization supported managers to collaborate with their teams to design schedules that best accommodated the new work-from-home lifestyles. Our psychosocial team also stepped in to give counseling services to staff members who required them, while our technology team worked swiftly to develop solutions that allowed secure remote access to our systems by the staff. In partnership with Mulago Specialised Women and Neonatal Hospital, a mass on-site immunisation of workers was undertaken in May 2021.

Ministry of Health nurse guides MU-JHU staff on the Client Consent Form for the COVID-19 vaccination

A Ministry of Health nurse administers the Astra Zeneca vaccine to MU-JHU staff members

B. Grants & Partnerships

Grants

MU-JHU Care Ltd has proactively worked towards expanded her scope of research science. This has encouraged our teams to seek diverse funding sources outside our traditional partnerships.

Despite the restrictive business environment created by the COVID-19 pandemic our Grants team worked with our Investigators to identify potential areas for health research. Exploring data patterns in our studies and Country Health statistics, the teams were able to strategically apply for several grants. We secured 5 in our new areas of interest, ourside of HIV research.

Grant Name	Funding Agency	MU-JHU Lead PI & Year of Submission
perCovid _Understanding COVID-19 infections in pregnant women and their babies in Uganda, Kenya, Malawi, the Gambia and Mozambique	EDCTP	Prof. Kirsty Le Doare 2020
Increasing Maternal Immunisation Awareness, by Working with Women Influencers in Kawempe Division, Uganda.	IMPRINT	Dr. Mary Kyohere 2020
TB-Speed Covid 19_substudy	ANRS	Dr. Eric Wobudeya 2020
Hospital-Based Birth Defects Surveillance Study In Kampala, Uganda	CDC	Prof. Philippa Musoke 2021
A Novel Video-Based Intervention to Enhance Optimal Uptake of Malaria Preventive Therapy: A Pilot Study of a Health Educational Approach to Malaria Prevention during Pregnancy.	NICHD	Dr. Rita Nakalega 2021

Partnerships in 2020-2021

We greatly value the partnerships we have cultivated over the years. With an ever expanding pool of science research organisations it is important to ensure that the alliances we make are going to serve our long term goals.

In the 2021, we maintained continuous engagement with the following organisations to support our collaborative efforts on research and program activities.

1. Johns Hopkins University
2. University of Minnesota
3. University of Iowa
4. Michigan State University
5. St George's University of London
6. Mulago National Referral Hospital
7. Kawempe National Referral Hospital
8. Baylor College of Uganda Children's Foundation
9. Infectious Diseases Institute (IDI)
10. Makerere University Joint AIDS Program (MJAP)
11. Uganda Cancer Institute (UCI)
12. Joint Clinical Research Centre (JCRC)
13. Infectious Diseases Institute (IDI) Core Lab
14. Medical and Molecular Laboratories Limited (MML)
15. Mityana General Hospital
16. Uganda Martyrs Hospital Lubaga
17. St. Francis Hospital Nsambya
18. Mengo Hospital

C. Regulatory Affairs Coordination

2021 Site Visits

Scheduled Monitoring Visits.					
Item #	Study	Monitoring Group	Scheduled Date	Study PI	Type
1.	PHOENix Study	PPD	8 – 19 February 2021	Dr.Carolyne Onyango	Remote
2.	HPTN-084	ViiV	11 – 19 February 2021	Dr. Clemensia Nakabiito	Onsite
3.	HPTN-084	PPD	11-19 February 2021	Dr. Clemensia Nakabiito	Remote
4.	MERIT Study	FHI Clinical	2-4 March 2021	Dr. Irene Lubega	Remote
5.	IMPAACT 2010	WESTAT	15– 20 March 2021	Dr. Deo Wabwire	Onsite
6.	MERIT study {Randomized Trial to Evaluate Mirasol Whole Blood Pathogen Reduction Technology System to Reduce Malaria and Other Transfusion Transmitted Infections } (Uganda Mirasol trail)	JCRC IRB	23 March 21	Dr. Irene Lubega	Onsite

Item #	Study	Monitoring Group	Scheduled Date	Study PI	Type
7.	TBSPEED [Impact of systematic early tuberculosis (TB) detection using Xpert MTB/RIF Ultra in children with severe pneumonia in high tuberculosis burden countries]	JCRC IRB	23 March 21	Dr. Eric Wobudeya	Onsite
8.	Maternal Repeat Pregnancy The Maternal Repeat Pregnancy Bone Health study protocol:	JCRC IRB	24 March 21	Dr. Flavia Matovu Kiweewa	Onsite
9.	TBSAM [Development of a Diagnostic Prediction Score for Tuberculosis Hospitalized Children with Severe Acute Malnutrition]	JCRC IRB	24 March 21	Dr. Eric Wobudeya	Onsite
2nd Quarter 2021					
13.	WoMANPOWER Study	CRA (onsite)	1-2 June 2021	Dr. Eva Nakabembe	Onsite
14.	IMPAACT 2010	WESTAT – Kenya	24-28 May 2021	Dr.Deo Wabwire	Onsite
15.	HPTN-084, MTN 042, MTN-034	PPD (from South Africa)	17 - 28 May 2021	Dr. Clemensia Nakabiito	Onsite
				Dr. Brenda Gati	Onsite
				Dr. Carolyne Akello	Onsite

Item #	Study	Monitoring Group	Scheduled Date	Study PI	Type
16.	PHOENIx	PPD	17 -21 May 2021	Dr. Carol Onyango	Onsite
17.	PHOENIx	PPD	5 - 9 Apr 2021	Dr. Carolyne Onyango	Remote
18.	Minervax	Sponsor site visit	12 – 14 April 2021	Dr. Musa Sekikubo	Onsite
19.	HPTN-084	ViiV	12-23 Apr 2021	Dr. Clemensia Nakabiito	Onsite
20.	MERIT	FHI Clinical	26 Apr – 12 May 2021	Dr. Irene Lubega	Remote

Chapter 3

FINANCE

Financial Performance Report

This report highlights MU-JHU's financial activities and results for the financial year period July 2020 to June 2021. The detailed report and auditor's opinion are in the Annex III.

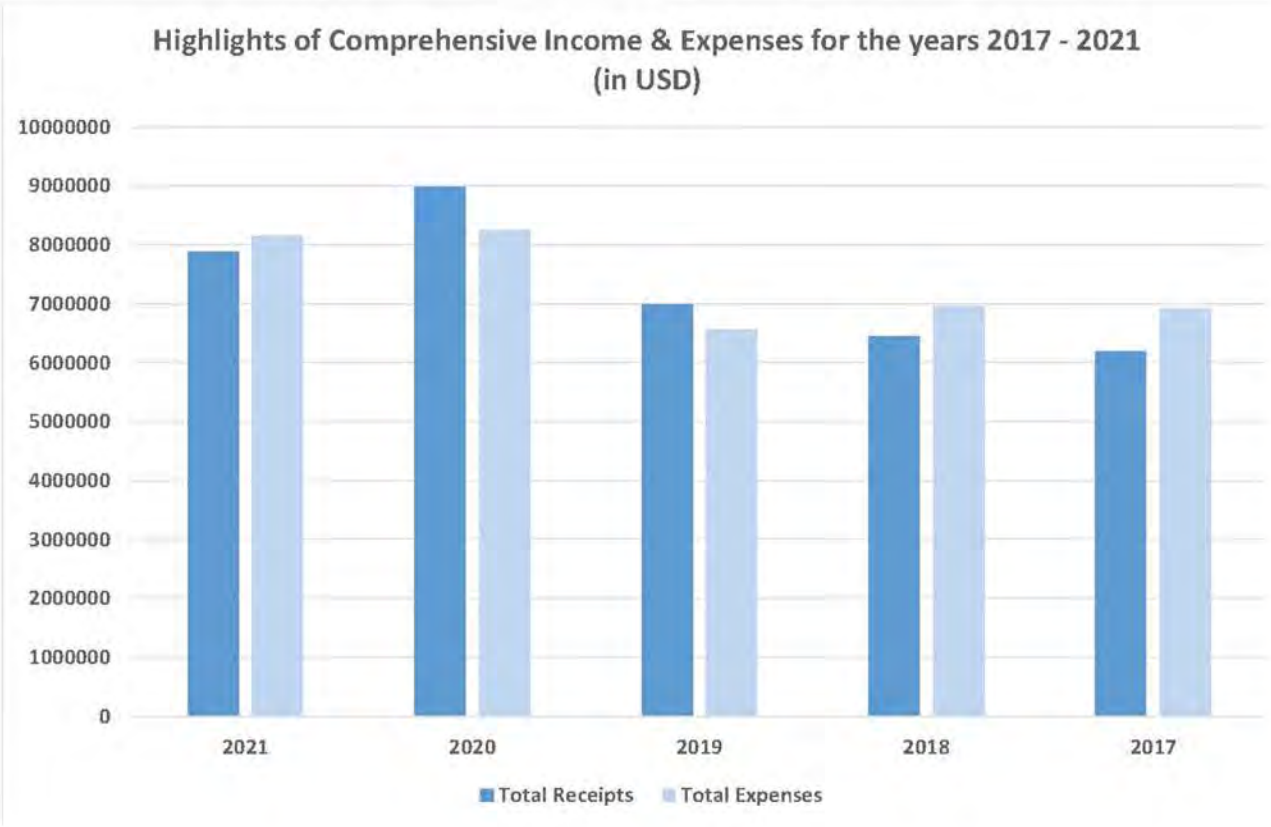
Executive Summary

- For the 12-month period July 01, 2020 to June 30 2021, the organisation's Reserve Funds balance rose to a record of $1,748,696, a 22% increase from last year. Of this amount, $1,122,769 is classified as unrestricted reserve funds.
- With the $1,122,769 unrestricted reserve funds, MU-JHU already achieve 62% of its target 3-month operational reserve of $1,800,000.
- However, MU-JHU's liquidity ratio had reduced from an average of 4.56 for the last 5-years to 3.10 as of end of financial year.

Financial Results

- Using a modified cash basis of accounting for transactions, MU-JHU reported a total operational expense of $8,147,856 for this period.
- This is equivalent to 99% of 2020 operational cost and 116% of average operational cost for the years 2016 – 2020.
- For this period, 64% of expenses were accounted as Personnel costs, while 12% are incurred for participant charges. A capital expenditure equivalent to 2% was also paid, while the remaining 22% was distributed amongst travel, supplies, community activities, sub-award and other costs.
- Due to in-country restrictions of activities during the period especially the lock-down of movements on June 2021, there was substantial increase in transport and supplies cost to support staff travel and procurement of preventive supplies against the COVID-19 virus.
- The capital expenditure included procurement of a new motor vehicle and set up of a new COVID-19 dedicated clinic to accommodate the upcoming COVID-19 studies. It also includes other refurbishments of clinical and office spaces for instance the Adolescent space, YGA office, Security.

- The reduced liquidity rate was highly attributed to the delay in collections from sponsors for those projects, under cost-reimbursement funding model.
- The table below shows comparative results of financial operations for the last five years using the Modified Cash basis of accounting in recording the transactions.



The core finance team

MU-JHU Care LTD Comparative Statement of Financial Position for 5 year period					
	2021 USD	2020 USD	2019 USD	2018 USD	2017 USD
Opening Balance Equity	1,136,324	398,615	(30,537)	477,966	1,199,233
Adjustment to the Fund Balance					
(Deficit) Surplus for the year	(268,931)	737,709	429,152	(508,523)	721,247
Accumulated Fund Balance	867,393	1,136,324	398,615	(30,537)	477,986
Represented By:					
Current Assets	-	-	-	-	-
Cash and Bank Balance	1,237,922	1,211,708	785,604	313,518	503,310
Advances to Partners	0	0	0	0	11,413
Staff Debtors	15,066	8,943	11,085	8,849	10,241
Other Debtors	29,292	93,643	16,914	15,394	25,026
Total Assets	1,282,280	1,314,294	813,603	337,761	549,990
Current Liabilities	-	-	-	-	-
Creditors	414,887	177,970	414,988	368,298	72,004
Total Liaibilities	414,887	177,970	414,988	368,298	72,004
Net Assets	867,393	1,136,324	398,615	(30,537)	477,986

Pictorial: Milestones


Certificate of Excellence for Conduct of HPTN 084

MU-JHU Research Collaboration (MUJHU CARE LTD) CRS

IS RECOGNIZED FOR INITIATING PARTICIPANT ENGAGEMENT ACTIVITIES (PEAS) TO ASSIST PARTICIPANTS WITH TRANSITIONING TO STEP 2

CONGRATULATIONS!

Presented in Gratitude on 17 September 2020

HPTN

084

HPTN Network Awards

1st Site visit by Incoming BoardChairman Dr. Samuel Okware

Hosted our first ever hybrid stakeholders meeting for the IMPOWER-022 Study

Launch of the Johns Hopkins University (JHU-CTU) Clinical Trials Unity Hub launch. A resource centre for all CTU-sites learning and engagement

Acknowledgements

We thank our Board of Directors, our Senior Management team, our members of staff, the Community Advisory board, the Institute Review Boards, our clinic research networks, our partners, Ministry of Health and the Government of Uganda. We also acknowledge our study participants and the larger communities from which they hail, for trusting us through the unprecedented Global COVID-19 pandemic.

As we move into our 2021-2022 financial year, we continue to engage in innovations that address predominate health concerns in Uganda and the provision quality research data. We also remain passionate about enriching the lives of our participants, in ways that are sustainable beyond the research cycle. We aim do this by remodeling our strategic planning function, increasing our grants portfolio, strengthening our HR training mandate and upgrading our facilities (infrastructure and technology).

Senior Management Team, Investigators and past research participants pose with the new Board Chairman, Dr. Samuel Okware, during his first site visit as chairman in January 2021.

Annexes

Annex I: MU-JHU Studies

Surveillance Studies	Birth Defects Surveillance
Paediatric & Adult HIV treatment & prevention trials	Paediatrics Studies • Odyssey (PENTA 50) • Odyssey Youth Trial Board • Deciphering Mechanisms of HIV Latency Reversal in Perinatal Infections Adult Studies • PROMOTE • PROMOTA • CD PROMOTE • GC ICODA pilot Initiative • PeriCovid • HPTN-084 • MTN-042
Paediatric & Adult TB treatment& prevention clinical trials	Paediatrics • SHINE • TB-SPEED • TB SURE Adult • PHOENiz MDR TB Study
Neurodevelopment studies	• The PROMISE Neurodev Study • The Neurodevelopment Brain Powered Games Study
Drug dose-finding studies (PK/PD)	IMPAACT • IMPAACT 1093 • IMPAACT P1115 • P1026 MTN • MTN-034 Study • MTN-043 Study • MTN-045 Study HPTN • HPTN 084 Study • HPTN 084-01 Study CoVPN • CoVPN 3005 Study
Treatment and Prevention techniques and technologies	MERIT (Mirasol Evaluation of Reduction in Infections Trial)
Bone Health studies	BONE: CARE Study BONE Star Maternal Repeat Pregnancy Bone Health Study
Vaccine-related studies	NeoObs PROGRESS WoMANPOWER (DTAP) Study Prepare Consortium IMPRINT TIMING (HicVac)

Annex II: List of Abbreviations & Acronyms

AIDS	Acquired Immunodeficiency Syndrome
AGYW	Adolescent girls and young women
ANRS	French Agency for Research on AIDS and Viral Hepatitis
CAB	Community Advisory Board
CDC	The Centers for Disease Control and Prevention
COVID-19	Coronavirus disease 2019
COVPN	COVID-19 Prevention Network
EDCTP	The European and Developing Countries Clinical Trials Partnership
HPTN	HIV Prevention Trials Network
HIV	Human Immunodeficiency Virus
IMPAACT	International Maternal, Pediatric, Adolescent AIDS Clinical Trials
IMPRINT	Immunising pregnant women and infants (IMPRINT) Network
iNSC	Integrated next step counseling
IRB	Institutional Review Board
JCRC	Joint Clinical Research Centre
MTN	Microbicide Trials Network
MU-JHU	Makerere University- Johns Hopkins University
NICHD	The Eunice Kennedy Shriver National Institute of Child Health and Human Development
PI	Principle Investigator
PPD	Pharmaceutical Product Development
SLF	Stephen Lewis Foundation
SHINE	Shorter Treatment for Minimal Tuberculosis in Children
SOPS	Standard Operations Procedures
TB	Tuberculosis
YGA	Young Generation Alive
YTB	Youth Trials Board

Follow MU-JHU Care Ltd on Facebook, Twitter, and Instagram to catch report highlights and for information on our research, programs and community engagements.

For additional information, please contact:

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MU-JHU CARE LTD
MU-JHU RESEARCH COLLABORATION

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