

Building Novel Clinical Research Capacity in Resource-Limited Settings: Lessons Learned at Three Mozambique Sites

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BACKGROUND

There are striking disparities in clinical research capabilities worldwide, particularly across regions of sub-Saharan Africa, where disease burden is high. Establishment of novel, indigenous research capabilities is difficult, and evaluations of capacity-building efforts remain scarce. We share our lessons learned from establishing three new clinical research sites in Mozambique.

METHODS

Three new clinical research sites were successfully established in Mozambique. These sites are located in Maputo (capital city), Chókwè (Gaza province) and Beira (Sofala province). Clinical research capacity building was mainly achieved through the implementation of HIV-related clinical trials and epidemiological studies. It took two years between initial discussions and study initiation.

Figure 1: Map of Mozambique



Figure 2: HIV/AIDS Awareness Event, Mozambique



Agreed upon methods included:

Obtaining political (Health Minister, National Institute of Health, provincial, district and municipal approvals) and institutional review boards/ethics committee approvals

Creation of laboratory infrastructure

Creation of data management infrastructure

Establishment of clinical infrastructure

Establishment of financial management systems

Recruitment, training and retention of critical research staff

Development of links for community support, participant recruitment, retention and referrals

Marketing of research sites to outside funders

Strengthening of human research subjects committees

RESULTS

Sites established:

Maputo: CISPOC/INS



Polana Caniço Health Research and Training Center/Centro de Investigação e Treino em Saúde da Polana Caniço (CISPOC), Maputo Province

Established in 2011, affiliated with National Institute of Health (INS)/Ministry of Health

Phase 1 HIV vaccine trial; biomedical studies and evaluation of new laboratory technologies

Chókwè: CITSC/INS



Chókwè Health Research and Training Center/Centro de Investigação e Treino em Saúde de Chókwè (CITSC), Gaza Province

Established in 2007, affiliated with National Institute of Health (INS)/Ministry of Health

Phase III trial of new fixed combination of anti-malarials, HIV incidence study (BED false recent phase, cross-sectional survey and prospective cohort study) , Health Demographic Surveillance Survey (HDSS)

Beira CIDI/UCM



Center for Infectious Disease Research/Centro de Investigação de Doenças Infecciosas (CIDI), Sofala Province

Established in 2008, affiliated with the Catholic University of Mozambique/Universidade Católica de Moçambique (UCM), private medical university

HIV incidence study (BED false recent phase, cross-sectional survey and prospective cohort study)

Current Research Capacity:

Maputo: CISPOC/INS

25 staff
Clinical research laboratory
Six private medical/examination rooms
Two counseling rooms
Data management unit
Office space/waiting area/reception
Pharmacy
Administrative area
Community mobilization unit
Conference/training rooms

Chókwè: CITSC/INS

68 staff
Clinical research laboratory
Two private medical/examination rooms
Four counseling rooms
Data management unit
Office space/waiting area/reception
Community mobilization unit
Administrative area
Health demographic surveillance platform/
Geographic information systems

Beira: CIDI/UCM

30 staff
Clinical research laboratory (including access to TB culture)
Five private medical/examination/counseling rooms
Data management unit
Office space/waiting area/reception
Community mobilization unit
Administrative area

Capacity building success depended on:

Alignment with national and institutional priorities

Areas of high HIV incidence with potential for future prevention research

Strong local leadership with locally-based management teams

Local ownership of capacity building effort and field site philosophy

Creation of career paths, careful selection of and sustained training of staff

Containment of research costs, leveraging of funds and diversification of research portfolio

Collaborative spirit and careful transitions of sites from one funder to another

Balanced combination of biomedical and community-based field research for systemic capacity building

Patience with time horizons and long-term visions involved with building novel research capacity in resource-limited settings

Time horizons:

	CISPOC/INS Maputo	CITSC/INS Chókwè	CIDI/UCM Beira
November-08	INS approval for research capacity building	INS approval for research capacity building	INS approval for research capacity building
January-07	INS starts field preparation for implementation of Phase III TB/HIV treatment study	INS starts field preparation for implementation of Phase III TB/HIV treatment study	INS starts field preparation for implementation of Phase III TB/HIV treatment study
February-07	Staff hiring process begins for TB/HIV study	Staff hiring process begins for TB/HIV study	Staff hiring process begins for TB/HIV study
April-07	Conducts a health census of Maputo city	Conducts a health census of Maputo city	Conducts a health census of Maputo city
June-07	Training of staff: Good Clinical Practice, Good Clinical Laboratory Practice and study procedures	Training of staff: Good Clinical Practice, Good Clinical Laboratory Practice and study procedures	Training of staff: Good Clinical Practice, Good Clinical Laboratory Practice and study procedures
June-07	First site begins recruitment for TB/HIV study	First site begins recruitment for TB/HIV study	First site begins recruitment for TB/HIV study
January-08	Second site begins recruitment for TB/HIV study	Second site begins recruitment for TB/HIV study	Second site begins recruitment for TB/HIV study
March-08	Health Ministry approval for research capacity building	Health Ministry approval for research capacity building	Health Ministry approval for research capacity building
April-08	USAD concurrence received	USAD concurrence received	USAD concurrence received
April-08	PHI 360 - INS sub-agreement in place	PHI 360 - INS sub-agreement in place	PHI 360 - UCM sub-agreement in place
June-08	Third site begins recruitment for TB/HIV study	Third site begins recruitment for TB/HIV study	Third site begins recruitment for TB/HIV study
July-08	First technician trained on purification and freezing of PBMC, ELISPOT for HIV and T-cell proliferation	First technician trained on purification and freezing of PBMC, ELISPOT for HIV and T-cell proliferation	First technician trained on purification and freezing of PBMC, ELISPOT for HIV and T-cell proliferation
August-08	Initial discussions with Youth Clinic at Maputo Central Hospital (MCH) to conduct HIV incidence study	Initial discussions with UCM regarding laboratory space	Initial discussions with UCM regarding laboratory space
November-08	Initial HIV incidence protocol submissions to IRBs	Initial HIV incidence protocol submissions to IRBs	Initial HIV incidence protocol submissions to IRBs
December-08	Full IRB approval received for HIV incidence study	Full IRB approval received for HIV incidence study	Full IRB approval received for HIV incidence study
February-09	Full IRB approval received for HIV incidence study	Full IRB approval received for HIV incidence study	Full IRB approval received for HIV incidence study
March-09	CITSC/INS staff hiring process begins	CITSC/INS staff hiring process begins	CITSC/INS staff hiring process begins
April-09	CITSC/INS laboratory, data management and center rehabilitation begins	CITSC/INS laboratory, data management and center rehabilitation begins	CITSC/INS laboratory, data management and center rehabilitation begins
May-09	Staff hiring and training for HIV incidence cohort study	Staff hiring and training for HIV incidence cohort study	Staff hiring and training for HIV incidence cohort study
June-09	Good Clinical Practice and protocol procedures	Good Clinical Practice and protocol procedures	Good Clinical Practice and protocol procedures
September-09	INGO/UCM prospective HIV incidence cohort study initiated	INGO/UCM prospective HIV incidence cohort study initiated	INGO/UCM prospective HIV incidence cohort study initiated
October-09	Second technician trained on purification and freezing of PBMC, ELISPOT for HIV and T-cell proliferation	Second technician trained on purification and freezing of PBMC, ELISPOT for HIV and T-cell proliferation	Second technician trained on purification and freezing of PBMC, ELISPOT for HIV and T-cell proliferation
November-09	Equipment for assessment of immune response (ELISPOT Reader, NucleoCounter, liquid nitrogen containers and additional liquid nitrogen, water baths, incubators, centrifuges and freezers)	Equipment for assessment of immune response (ELISPOT Reader, NucleoCounter, liquid nitrogen containers and additional liquid nitrogen, water baths, incubators, centrifuges and freezers)	Equipment for assessment of immune response (ELISPOT Reader, NucleoCounter, liquid nitrogen containers and additional liquid nitrogen, water baths, incubators, centrifuges and freezers)
December-09	Equipment for assessment of immune response (ELISPOT Reader, NucleoCounter, liquid nitrogen containers and additional liquid nitrogen, water baths, incubators, centrifuges and freezers)	Equipment for assessment of immune response (ELISPOT Reader, NucleoCounter, liquid nitrogen containers and additional liquid nitrogen, water baths, incubators, centrifuges and freezers)	Equipment for assessment of immune response (ELISPOT Reader, NucleoCounter, liquid nitrogen containers and additional liquid nitrogen, water baths, incubators, centrifuges and freezers)
February-10	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study
March-10	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study
April-10	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study
May-10	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study	Recruitment completed for TB/HIV study

	CISPOC/INS Maputo	CITSC/INS Chókwè	CIDI/UCM Beira
June-10	INGO/UCM prospective HIV incidence cohort study recruitment completed	INGO/UCM prospective HIV incidence cohort study recruitment completed	INGO/UCM prospective HIV incidence cohort study recruitment completed
September-10	INGO/UCM prospective HIV incidence cohort study recruitment completed	INGO/UCM prospective HIV incidence cohort study recruitment completed	INGO/UCM prospective HIV incidence cohort study recruitment completed
October-10	INGO/UCM prospective HIV incidence cohort study recruitment completed	INGO/UCM prospective HIV incidence cohort study recruitment completed	INGO/UCM prospective HIV incidence cohort study recruitment completed
November-10	HIV vaccine trial (TABVAC-01) protocol submission to IRB + Two technicians were certified to perform ELISPOT	HIV vaccine trial (TABVAC-01) protocol submission to IRB + Two technicians were certified to perform ELISPOT	HIV vaccine trial (TABVAC-01) protocol submission to IRB + Two technicians were certified to perform ELISPOT
December-10	INGO/UCM site considered formally on INS research center	INGO/UCM site considered formally on INS research center	INGO/UCM site considered formally on INS research center
January-11	Recruitment ends for HIV/TB study	Recruitment ends for HIV/TB study	Recruitment ends for HIV/TB study
February-11	Acquisition of Flow Cytometer FACScan and MagNet Luminex	Acquisition of Flow Cytometer FACScan and MagNet Luminex	Acquisition of Flow Cytometer FACScan and MagNet Luminex
March-11	Staff hiring begins	Staff hiring begins	Staff hiring begins
April-11	Good Clinical Practice training	Good Clinical Practice training	Good Clinical Practice training
May-11	TABVAC-01 data management training	TABVAC-01 data management training	TABVAC-01 data management training
June-11	Site assessment for TABVAC-01 trial	Site assessment for TABVAC-01 trial	Site assessment for TABVAC-01 trial
July-11	Staff training on protocol procedures for Phase III HIV vaccine trial	Staff training on protocol procedures for Phase III HIV vaccine trial	Staff training on protocol procedures for Phase III HIV vaccine trial
August-11	Establishment of laboratory infrastructure	Establishment of laboratory infrastructure	Establishment of laboratory infrastructure
September-11	International course on GCP and GLP: Train the Trainers	International course on GCP and GLP: Train the Trainers	International course on GCP and GLP: Train the Trainers
October-11	Site initiates Phase III HIV vaccine trial	Site initiates Phase III HIV vaccine trial	Site initiates Phase III HIV vaccine trial
November-11	Public announcement of TABVAC-01 trial by the Minister of Health	Public announcement of TABVAC-01 trial by the Minister of Health	Public announcement of TABVAC-01 trial by the Minister of Health
December-11	CAPRICORN study pilot study on acute febrile surveillance	CAPRICORN study pilot study on acute febrile surveillance	CAPRICORN study pilot study on acute febrile surveillance
January-12	INGO/UCM prospective HIV incidence cohort study completed follow-up completed	INGO/UCM prospective HIV incidence cohort study completed follow-up completed	INGO/UCM prospective HIV incidence cohort study completed follow-up completed
February-12	Third training of additional one technician on purification, freezing, thawing and counting of cells using a NucleoCounter + First technician trained on flow cytometry using Flow Cytometer FACScan	Third training of additional one technician on purification, freezing, thawing and counting of cells using a NucleoCounter + First technician trained on flow cytometry using Flow Cytometer FACScan	Third training of additional one technician on purification, freezing, thawing and counting of cells using a NucleoCounter + First technician trained on flow cytometry using Flow Cytometer FACScan
March-12	CAPRICORN reaches recruitment targets for phase III HIV vaccine trial	CAPRICORN reaches recruitment targets for phase III HIV vaccine trial	CAPRICORN reaches recruitment targets for phase III HIV vaccine trial
April-12	TABVAC-01 begins development of a quality management plan	TABVAC-01 begins development of a quality management plan	TABVAC-01 begins development of a quality management plan
May-12	CAPRICORN starts HIV-1C vaccine cohort development program with MHRP	CAPRICORN starts HIV-1C vaccine cohort development program with MHRP	CAPRICORN starts HIV-1C vaccine cohort development program with MHRP
June-12	CAPRICORN starts HIV-1C vaccine cohort development program with MHRP	CAPRICORN starts HIV-1C vaccine cohort development program with MHRP	CAPRICORN starts HIV-1C vaccine cohort development program with MHRP

CONCLUSIONS AND RECOMMENDATIONS

Development of novel clinical research capacity in resource-limited settings is feasible, but considerable time and resources are required to create and manage productive sites. Partnerships between funding institutions is vital to provide financial stability and minimize risk.

DISCLOSURES

Authors of this presentation have nothing to disclose concerning possible financial or personal relationship with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

Nothing to disclose.

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