Site preparedness for clinical trials in Africa

Eusebio Macete
Manhica Health Research Centre, Mozambique
Africa’s contribution to the worldwide research literature: New analytical perspectives, trends, and performance indicators

ROBERT J. W. TİSSEN\textsuperscript{a, b}
<table>
<thead>
<tr>
<th>Country</th>
<th>ArCo index</th>
<th>Total publ. output</th>
<th>% int. co-publ.</th>
<th>Citation rate per publ.</th>
<th>% cited publ.</th>
<th>Relative citation scores Field-norm.</th>
<th>Journal-norm.</th>
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<td>South Africa</td>
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<td>Kenya</td>
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<td>2067</td>
<td>74</td>
<td>1.89</td>
<td>45%</td>
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<td>Algeria</td>
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<td>58</td>
<td>0.73</td>
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<td>Ghana</td>
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<td>Senegal</td>
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<td>73</td>
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<td>0.81</td>
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<td>Botswana</td>
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<td>422</td>
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<td>0.53</td>
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<td>Malawi</td>
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<td>0.76</td>
<td>0.78</td>
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<td>Burkina Faso</td>
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<tr>
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<td>26%</td>
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<td>Niger</td>
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<td>126</td>
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<td>40%</td>
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<td>Mozambique</td>
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<td>36%</td>
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<td>Togo</td>
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<td>101</td>
<td>66</td>
<td>0.99</td>
<td>33%</td>
<td>0.63</td>
<td>0.47</td>
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</table>

Source: CITES (2017) Science Citation Index, journal and field normalized 2003 results (h-index = 68 in science).
ACORDO GERAL DE COOPERAÇÃO CIENTÍFICA E TÉCNICA
ENTRE O GOVERNO DA REPÚBLICA POPULAR DE MOÇAMBIQUE E O GOVERNO DE ESPANHA

O Governo da República Popular de Moçambique e o Governo de Espanha conscientes da necessidade de uma estreita cooperação entre ambos...
LOCATION OF MANHICA DSS SITE, MOZAMBIQUE, 36,000

Mozambique
Manhica District
DSS Site
Research Activities

- Malaria
- HIV/AIDS
- TB
- Diarrheal diseases
- Pneumonias and Invasive Bacterial Disease

Clinical and molecular epidemiology

Maternal and Reproductive Health

Social Sciences

Monitoring and evaluation

Clinical Trials Unit
1996 there were few groups doing research in the country

There was no capacity for Clinical trials

The first studies at CISM were more focused on Epidemiology
Malaria in pregnancy in rural Mozambique: the role of parity, submicroscopic and multiple *Plasmodium falciparum* infections

Francisco Saute¹, Clara Menendez¹,², Alfredo Mayor¹,², John Aponte¹,², Xavier Gomez-Olive¹,², Martinho Dgedge¹ and Pedro Alonso¹,²

1 Centro de Investigação em Saúde da Manhiça, Instituto Nacional de Saúde, Maputo, Mozambique
2 Unidad de Epidemiologia y Biostadística, Institut d’Investigacions Biomèdiques August Pi i Sunyer, Barcelona, Spain

Vaccine-related HPV genotypes in women with and without cervical cancer in Mozambique: Burden and potential for prevention

Xavier Castellsague¹, JoEllen Klaustermeier¹, Carla Carrilho²,³, Ginesa Albero¹, Jahit Sacarlal⁴,⁵, Wim Quint⁶, Bernhard Kleter⁷, Belen Lloveras¹, Mamudo Rafik Ismail²,³, Silvia de Sanjose¹, F. Xavier Bosch¹, Pedro Alonso⁴,⁶ and Clara Menéndez⁴,⁶

¹IDIBELL, Institut Català d’Onologia (ICO), L’Hospitalet de Llobregat, Barcelona, Spain
²Department of Pathology, Maputo Central Hospital, Maputo, Mozambique
³Department of Pathology, Faculty of Medicine, University Eduardo Mondlane, Maputo, Mozambique
⁴The Manhiça Health Research Center (CISM), Manhiça, Mozambique
⁵DDL Diagnostic Laboratory, Voorburg, The Netherlands
⁶Barcelona Center for International Health Research (CRESIB), Institut d’Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Universitat de Barcelona, Barcelona, Spain
ID Perm: 2602-031-06

GIS

All study forms

MSS  NIDA  Lab IS  DSS
What next?
Safety and immunogenicity of the RTS,S/AS02A candidate malaria vaccine in children aged 1–4 in Mozambique

E. Macete¹,²,³, J. J. Aponte¹,², C. Guinovart¹,², J. Sacarlal¹,²,⁴, O. Ofori-Anyinam⁵, I. Mandomando¹,²,⁶, M. Espasa¹,²,⁶, C. Bevilacqua⁵, A. Leach⁵, M. C. Dubois⁵, D. G. Heppner⁷, L. Tello¹,², J. Milman⁸, J. Cohen⁵, F. Dubovsky⁸, N. Tornieporth⁵, R. Thompson¹,⁴,⁶ and P. L. Alonso¹,²,⁶
<table>
<thead>
<tr>
<th></th>
<th>CQ (n = 85)</th>
<th>SP (n = 81)</th>
<th>AQ (n = 83)</th>
<th>AQSP (n = 60)</th>
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<th>AQAR (n = 53)</th>
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<tr>
<td>n (%)</td>
<td>40 (47.1)</td>
<td>67 (82.7)</td>
<td>76 (91.6)</td>
<td>60 (100)</td>
<td>53 (100)</td>
<td>53 (100)</td>
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<tr>
<td>95% CI</td>
<td>36.1; 58.2</td>
<td>72.7; 90.2</td>
<td>83.4; 96.5</td>
<td>94; 100</td>
<td>93.3; 100</td>
<td>93.3; 100</td>
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<tr>
<td>ETF</td>
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<tr>
<td>n (%)</td>
<td>22 (25.9)</td>
<td>11 (13.6)</td>
<td>4 (4.8)</td>
<td>0</td>
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<td>0</td>
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<tr>
<td>95% CI</td>
<td>16.9; 36.5</td>
<td>6.98; 23.0</td>
<td>0.13; 11.8</td>
<td>0; 5.9</td>
<td>0; 6.7</td>
<td>0; 6.7</td>
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<tr>
<td>LTF</td>
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<tr>
<td>n (%)</td>
<td>23 (27.1)</td>
<td>3 (3.7)</td>
<td>3 (3.6)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>95% CI</td>
<td>17.9; 37.8</td>
<td>0.77; 10.4</td>
<td>0.75; 10.2</td>
<td>0; 5.9</td>
<td>0; 6.7</td>
<td>0; 6.7</td>
</tr>
</tbody>
</table>

ACR, adequate clinical response; ETF, early treatment failure; LTF, late treatment failure.
Human Capacity
✓ The Centre has collaboration with different academic institutions

Supported by
AECID
Clinical Trials (RTS,S)
EDCTP
Gates Foundation
INDEPTH

- Workshops and seminars
- Continuous training
Infrastructure
Data collection

CISM DATA CENTRE (Manhica) APPLICATIONS SERVER DATABASE

Demographic Surveillance System Application
Healthcare System Application

Birth Form
Death Form
In-migration Form
Out-migration Form
Correct and Update data
Pregnancy Form
Pregnancy Outcome Form

GPS Coordinates

Household Member(s)

Manhica Health

Patient(s)

Complete OPD and/or INPD Forms Application

Router
Complete OPD Form Application

Satellite

7/14/2014
Microbiology Lab
Lab. capacity
Quality
Institutional
✓ The need of a Mozambican legal structure to manage the CISM was identified as key for its sustainability

✓ This legal structure needed to provide long-term sustainability and autonomy while keeping the center’s main stakeholders engaged

✓ As a result, the Manhiça Foundation was created in February 2008
Manhiça Foundation

Board of Trustees
President: Dr. Pascoal M. Mocumbi

Board of Governors
President: Prof. Pedro L. Alonso

Director
Dr. Eusébio V. Macete

Scientific area
Services area
Training area
Administration and Finance area

CISM
Legal capacity

The Contracting Parties also agree that, unless otherwise stipulated in the following, all data and results generated during the trial will belong exclusively to both the Sponsor and the Trial Site.

Administration

✓ Salaries (local and expatriate personal)

✓ Training vs Staff retention
PRINCIPAIS FINANCIADORES

- AECID (SPANISH INTERNATIONAL DEVELOPMENT AGENCY) 33%
- PATH MALARIA VACCINE INITIATIVE (MVI) 22%
- BMGF (BILL & MELINDA GATES FOUNDATION) 8%
- MARYLAND UNIVERSITY 7%
- EDCTP (EUROPEAN AND DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP) 5%
- LSTM (LIVERPOOL SCHOOL OF TROPICAL MEDICINE) 5%
- INDEPTH 3%
- AREAS 3%
- BROAD INSTITUTE 2%
- DEUTSCHE FORSCHUNG (GERMAN RESEARCH FOUNDATION) 1%
- USAID (UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT) 1%

FNI and MISAU
Efficacy of the RTS,S/AS02A vaccine against *Plasmodium falciparum* infection and disease in young African children: randomised controlled trial

Pedro L. Alonso, Jahit Sacarlal, John J Aponte, Amanda Leach, Eusebio Macete, Jessica Milman, Inacio Mandomando, Bart Spiessens, Caterina Guinovart, Mateu Espasa, Quique Bassat, Pedro Aide, Opoku Ofori-Anyinam, Margarita M Navia, Sabine Corachan, Marc Ceuppens, Marie-Claude Dubois, Marie-Ange Demoitié, Filip Dubovsky, Clara Menéndez, Nadi Tomieporth, W Ripley Ballou, Ricardo Thompson, Joe Cohen

Intermittent Preventive Treatment for Malaria Control Administered at the Time of Routine Vaccinations in Mozambican Infants: A Randomized, Placebo-Controlled Trial

Eusebio Macete,1,2 Pedro Aide,1,3 John J. Aponte,1,5 Sergi Sanz,1,5 Inacio Mandomando,1,3 Mateu Espasa,1,5 Betuel Sigaque,1,3 Carlota Dobaño,6 Samuel Mabunda,2,4 Martinho DeDede,2,4 Pedro Alonso,1,6 and Clara Menéndez1,6

1Manhiça Health Research Center, Manhiça, and 2National Directorate of Health, 3National Institute of Health, 4National Malaria Control Program, and 5Community Health Department, Ministry of Health, Maputo, Mozambique; 6Cancer for International Health, Hospital Clinic, Institut d’Investigacions Biomàdiques August Pi i Sunyer, University of Barcelona, Spain
Impact

Rate per 1000 live births

Year

2001 2006 2011

Under five mortality rate

Infant mortality rate

Neonatal mortality rate

250
200
150
100
50
0

202.6 135 99
88.8 72.7 55.8
30.1 28.1 22.5
0 50 100 150 200 250

2001 2006 2011
6 MATURE ALL-PURPOSE SITES

1. US Army Medical Research Project-Kenya (USAMRU-K), Kisumu (Kenya)
2. Wellcome Trust/KEMRI, Kilifi (Kenya)
3. Malaria Research and Training Centre (MRTC), Bancoumana, Bandiagara, Doneguebougou (Mali)
4. Centro de Investigação em Saúde da Manhiça (CISM), Manhiça (Mozambique)

5 SITES BEING UPGRADED

1. CDC/ KEMRI (Kenya)
2. Malaria Research Laboratory (MRL), University of Ibadan (Nigeria)
3. Noguchi Memorial Institute for Medical Research Clinical Trials Facility (Ghana)
4. Service de Parasitologie, University Cheikh Anta Diop, Dakar (Senegal)
5. Niakhar Institut de recherche pour le developpement, Niakhar, Dakar (Senegal)
Building Research Capacity in Africa: Equity and Global Health Collaborations

Kathryn M. Chu¹*, Sudha Jayaraman², Patrick Kyamanywa³, Georges Ntakiyiruta³

1 Center for Surgery and Public Health, Brigham and Women’s Hospital, Harvard Medical School, Department of Surgery, Boston, Massachusetts, United States of America, 2 Virginia Commonwealth University Medical Center, Department of Surgery, Richmond, Virginia, United States of America, 3 University of Rwanda, School of Medicine, Department of Surgery, Butare, Rwanda

1. How can African institutions and physicians benefit from international research collaborations without being exploited?

2. How can advancement of African research capacity and academic careers be prioritized while satisfying the “publish or perish” mandate of HIC universities?

3. How do African scientists and governments coordinate the great influx of HIC academics who view the continent as the next frontier in global health research?
Professor fellowship
www.manhica.org