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# **Site preparedness for clinical trials in Africa**

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Manhica Health Research Centre, Mozambique



**TESA**

TRIALS OF EXCELLENCE IN SOUTHERN AFRICA

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## **Africa's contribution to the worldwide research literature: New analytical perspectives, trends, and performance indicators**

ROBERT J. W. TIJSSEN<sup>a,b</sup>

Table 1. Bibliometric performance profiles of African countries: summary statistics (2001–2004)\*, \*\*

Country	ArCo index	Total publ. output	% int. co-publ.	Citation rate per publ.	% cited publ.	Relative citation scores***	
						Field-norm.	Journal-norm.
South Africa	0.37	14809	39	1.56	40%	0.63	0.90
Egypt	0.27	9895	29	0.81	31%	0.45	0.78
Morocco	0.22	3535	56	0.82	30%	0.43	0.69
Tunisia	0.29	2857	48	0.75	26%	0.44	0.68
Nigeria	0.14	2309	30	0.86	24%	0.47	0.78
Kenya	0.20	2067	74	1.89	45%	0.8	0.80
Algeria	0.28	2028	58	0.73	23%	0.51	0.70
Ghana	0.20	641	80	1.68	39%	0.78	0.86
Senegal	0.15	618	74	1.42	38%	0.74	0.82
Ivory Coast	0.14	449	73	1.46	37%	0.75	0.81
Botswana	0.26	422	41	0.98	30%	0.53	0.75
Malawi	0.13	413	73	2.08	49%	0.76	0.78
Burkina Faso	0.05	364	80	1.50	40%	0.69	0.82
Sudan	0.14	315	63	1.44	40%	0.68	0.92
Zambia	0.24	286	80	2.03	49%	0.75	0.71
Mauritius	0.29	153	53	1.56	26%	0.63	0.43
Namibia	0.22	145	56	1.93	34%	0.48	0.31
Congo Rep.	0.21	135	79	1.26	34%	0.75	0.53
Niger	0.03	126	66	1.53	40%	0.87	0.56
Mozambique	0.10	118	82	2.63	36%	0.85	1.06
Togo	0.15	101	66	0.99	33%	0.63	0.47



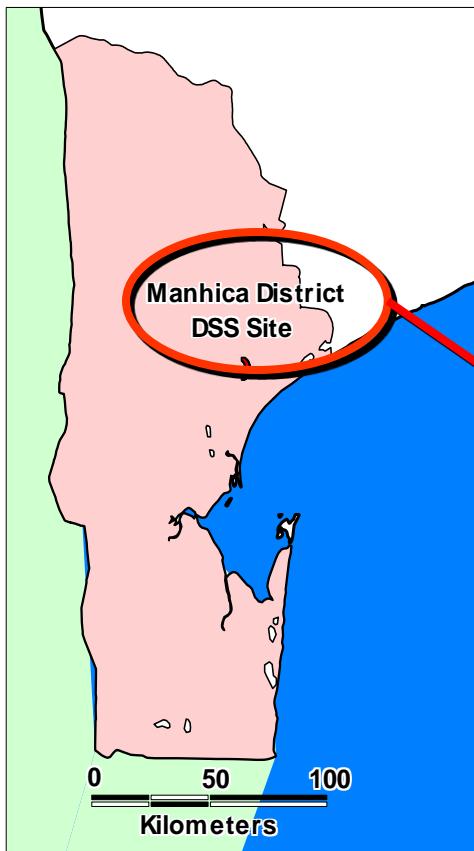
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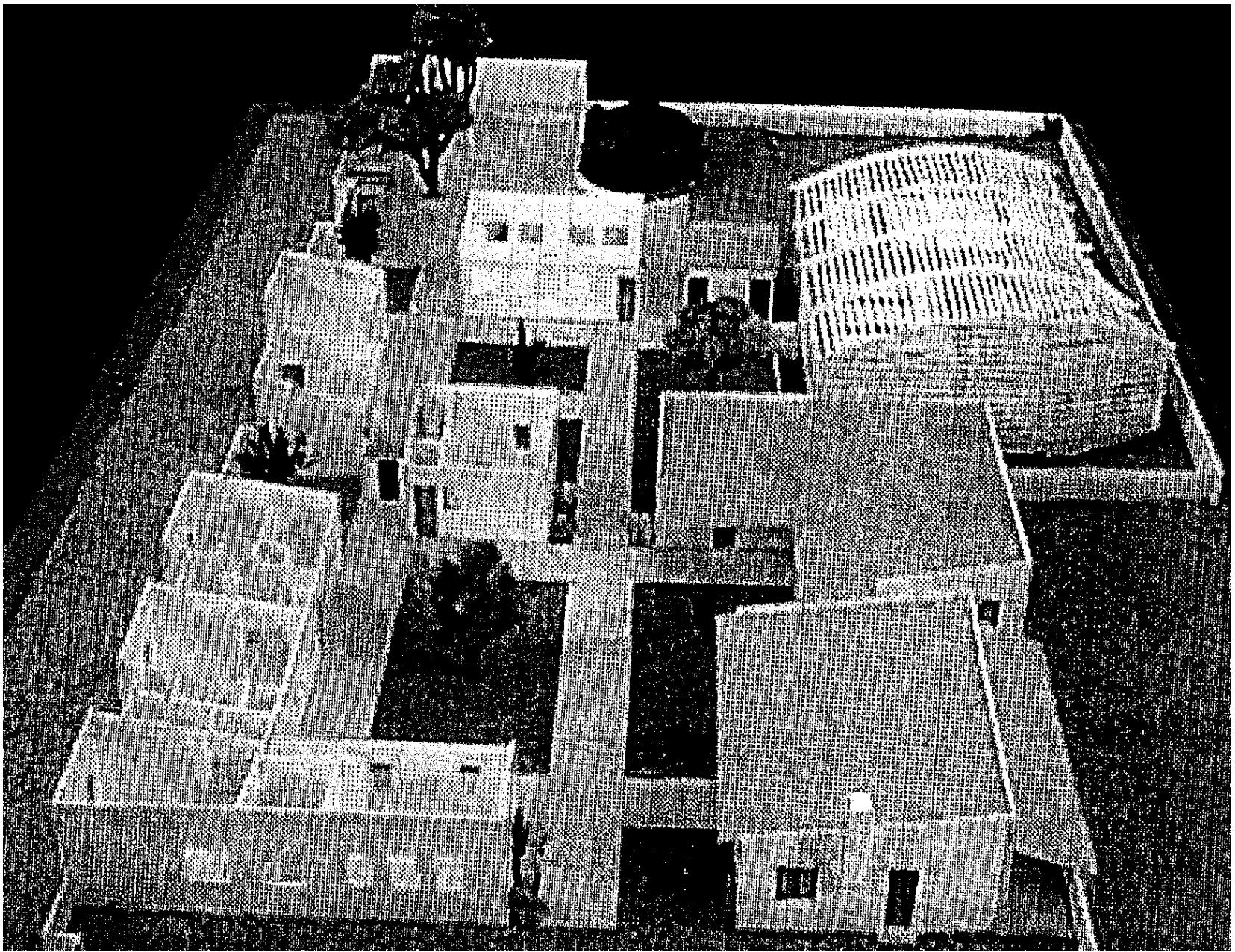
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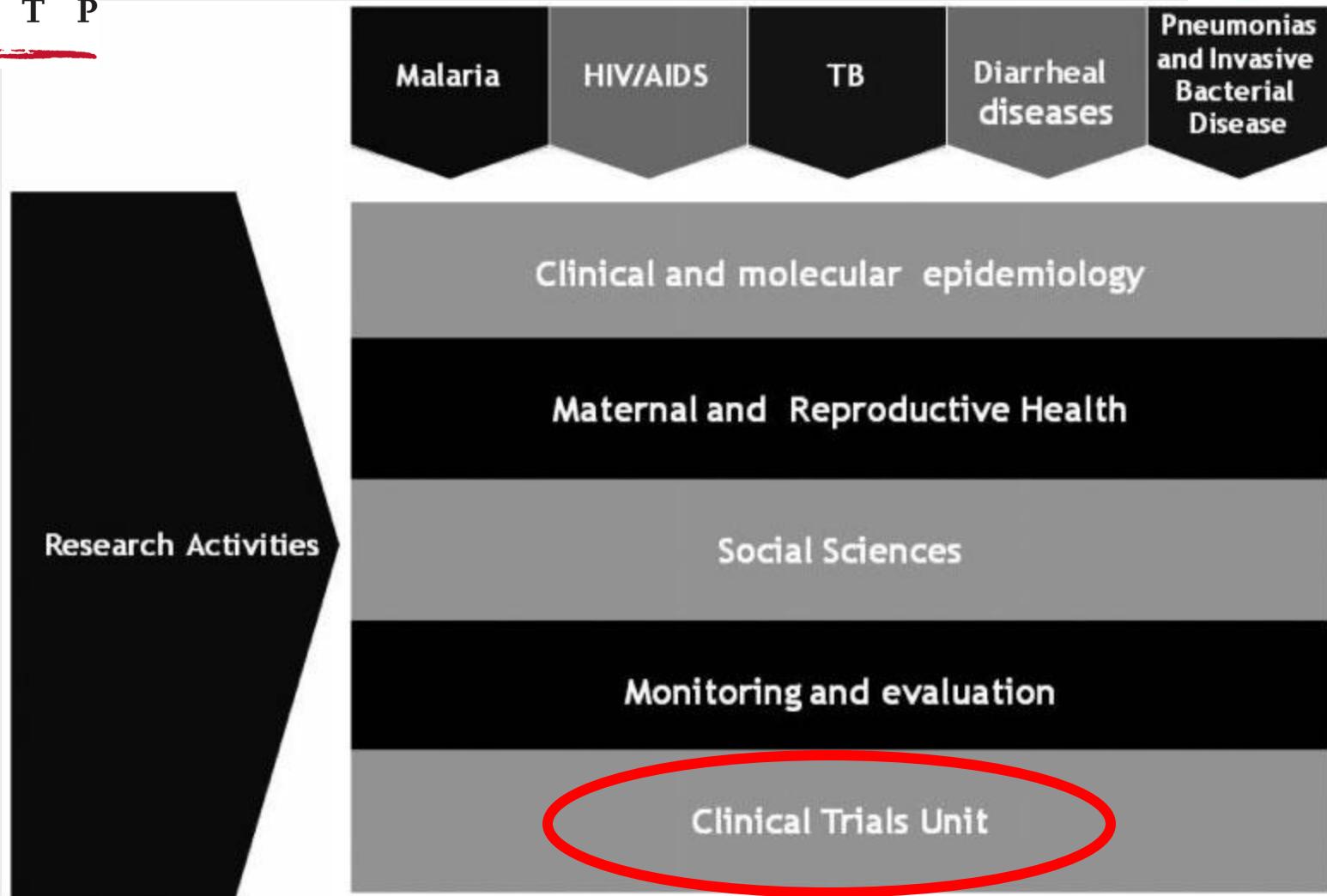
ACORDO GERAL DE COOPERAÇÃO CIENTÍFICA E TÉCNICA  
ENTRE O GOVERNO DA REPÚBLICA POPULAR DE MOÇAMBI-  
QUE E O GOVERNO DE ESPANHA

O Governo da República Popular de Moçambique e o Governo  
de Espanha conscientes da necessidade de uma estreita cooperação  
entre ambos,



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E D C T P



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- ✓ 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



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## Malaria in pregnancy in rural Mozambique: the role of parity, submicroscopic and multiple *Plasmodium falciparum* infections

Francisco Saute<sup>1</sup>, Clara Menendez<sup>1,2</sup>, Alfredo Mayor<sup>1,2</sup>, John Aponte<sup>1,2</sup>, Xavier Gomez-Olive<sup>1,2</sup>, Martinho Dgedge<sup>1</sup> and Pedro Alonso<sup>1,2</sup>

1 Centro de Investigação em Saúde da Manhiça, Instituto Nacional de Saúde, Maputo, Mozambique

2 Unidad de Epidemiología 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 Castellsague<sup>1\*</sup>, JoEllen Klaustermeier<sup>1</sup>, Carla Carrilho<sup>2,3</sup>, Ginesa Albero<sup>1</sup>, Jahit Sacarlat<sup>3,4</sup>, Wim Quint<sup>5</sup>, Bernhard Kleter<sup>5</sup>, Belen Lloveras<sup>1</sup>, Mamudo Rafik Ismail<sup>2,3</sup>, Silvia de Sanjosé<sup>1</sup>, F. Xavier Bosch<sup>1</sup>, Pedro Alonso<sup>4,6</sup> and Clara Menéndez<sup>4,6</sup>

<sup>1</sup>IDIBELL, Institut Català d'Oncologia (ICO), L'Hospitalet de Llobregat, Barcelona, Spain

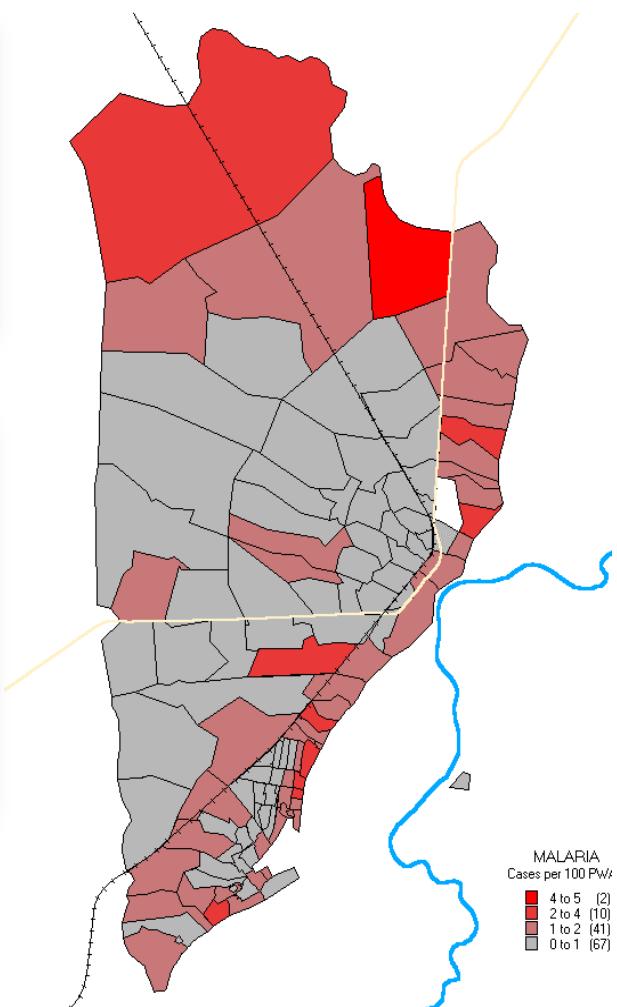
<sup>2</sup>Department of Pathology, Maputo Central Hospital, Maputo, Mozambique

<sup>3</sup>Department of Pathology, Faculty of Medicine, University Eduardo Mondlane, Maputo, Mozambique

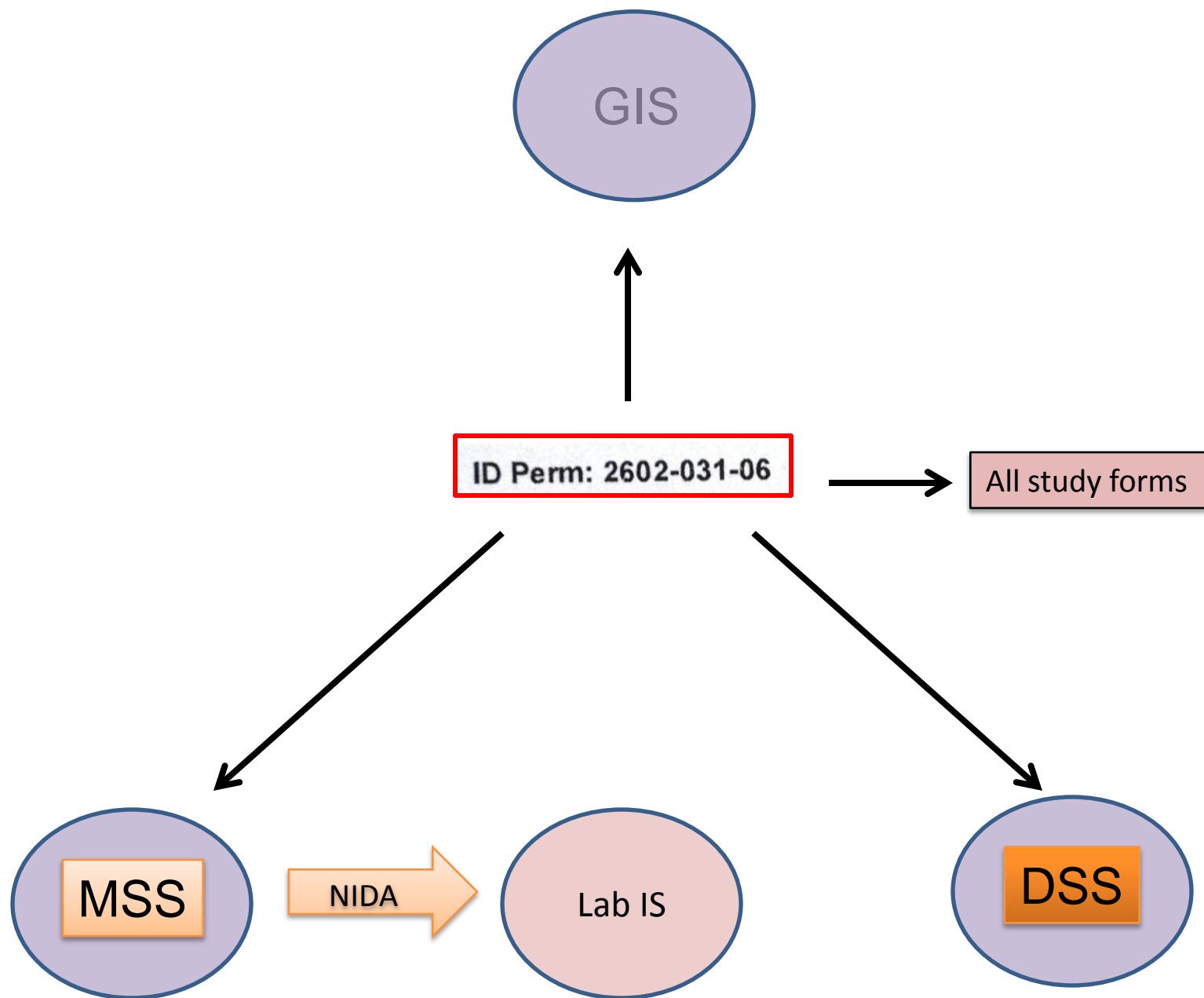
<sup>4</sup>The Manhiça Health Research Center (CISM), Manhiça, Mozambique

<sup>5</sup>DDL Diagnostic Laboratory, Voorburg, The Netherlands

<sup>6</sup>Barcelona Center for International Health Research (CRESIB), Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Universitat de Barcelona, Barcelona, Spain



Incidencia de Malaria ACD





# What next?



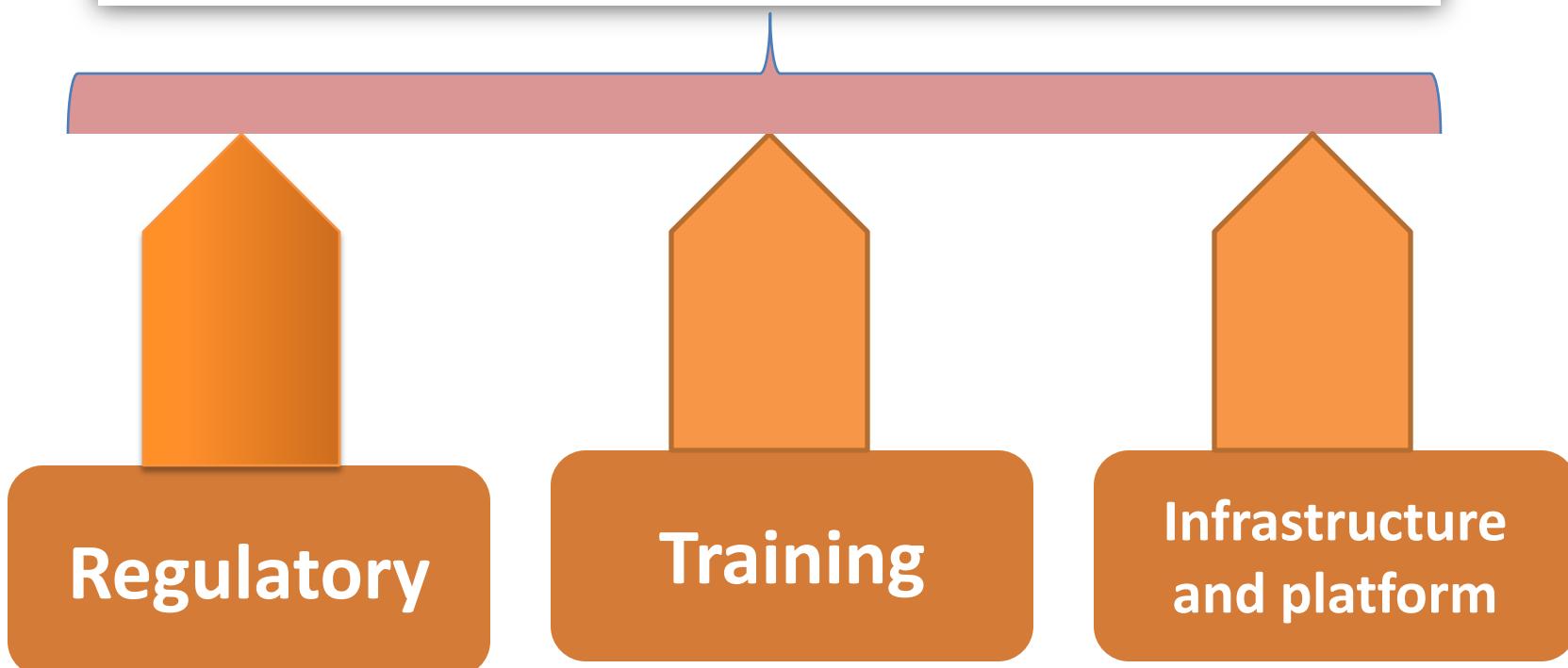
# 2002



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## Safety and immunogenicity of the RTS,S/AS02A candidate malaria vaccine in children aged 1–4 in Mozambique

E. Macete<sup>1,2,3</sup>, J. J. Aponte<sup>1,2</sup>, C. Guinovart<sup>1,2</sup>, J. Sacarlal<sup>1,2,4</sup>, O. Ofori-Anyinam<sup>5</sup>, I. Mandomando<sup>1,2,6</sup>, M. Espasa<sup>1,2,6</sup>, C. Bevilacqua<sup>5</sup>, A. Leach<sup>5</sup>, M. C. Dubois<sup>5</sup>, D. G. Heppner<sup>7</sup>, L. Tello<sup>1,2</sup>, J. Milman<sup>8</sup>, J. Cohen<sup>5</sup>, F. Dubovsky<sup>8</sup>, N. Tornieporth<sup>5</sup>, R. Thompson<sup>1,4,6</sup> and P. L. Alonso<sup>1,2,6</sup>



	CQ (n = 85)	SP (n = 81)	AQ (n = 83)	AQSP (n = 60)	ARSP (n = 53)	AQAR (n = 53)
<b>ACR</b>						
n (%)	40 (47.1)	67 (82.7)	76 (91.6)	60 (100)	53 (100)	53 (100)
95% CI	36.1; 58.2	72.7; 90.2	83.4; 96.5	94; 100	93.3; 100	93.3; 100
<b>ETF</b>						
n (%)	22 (25.9)	11 (13.6)	4 (4.8)	0	0	0
95% CI	16.9; 36.5	6.98; 23.0	0.13; 11.8	0; 5.9	0; 6.7	0; 6.7
<b>LTF</b>						
n (%)	23 (27.1)	3 (3.7)	3 (3.6)	0	0	0
95% CI	17.9; 37.8	0.77; 10.4	0.75; 10.2	0; 5.9	0; 6.7	0; 6.7

ACR, adequate clinical response; ETF, early treatment failure; LTF, late treatment failure.



# Human Capacity

# Training

- ✓ The Centre has collaboration with different academic institutions

Supported by

AECID

Clinical Trials (RTS,S)

EDCTP

Gates Foundation

INDEPTH

- Workshops and seminars
- Continuous training





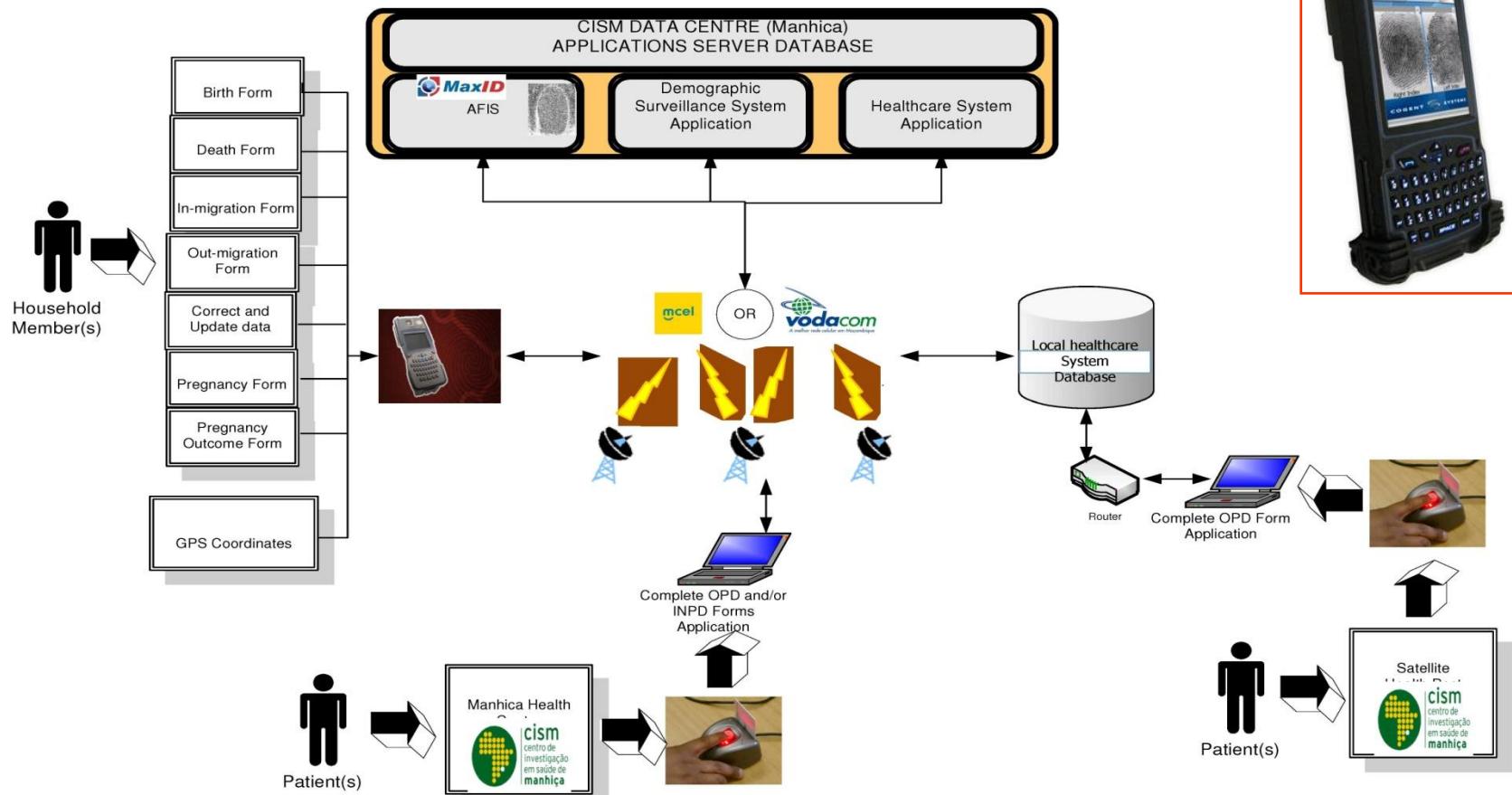
# Infrastructure



# Data collection



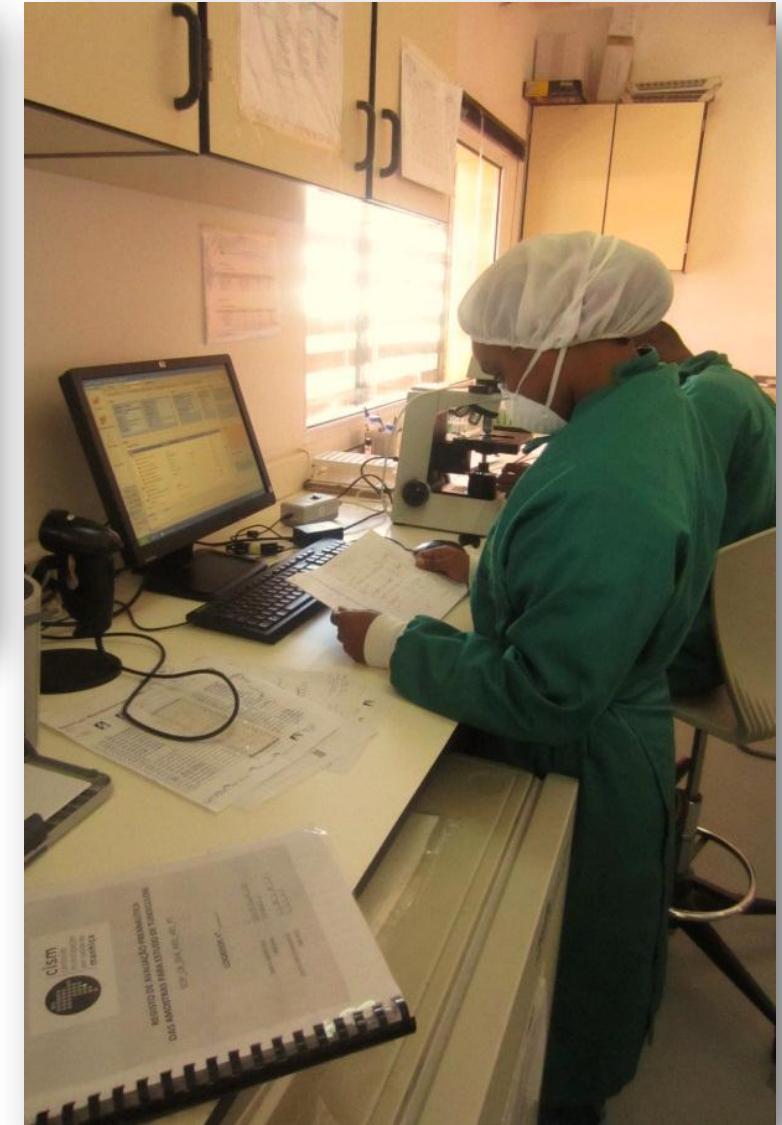
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# Microbiology Lab





# 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



fundaç<sup>ão</sup>  
**manhiça**  
moçambique



Board of Governors  
President: Prof. Pedro L. Alonso



Director  
Dr. Eusébio V. Macete

Scientific area

Services area

Training area

Administration and  
Finance area

## 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.

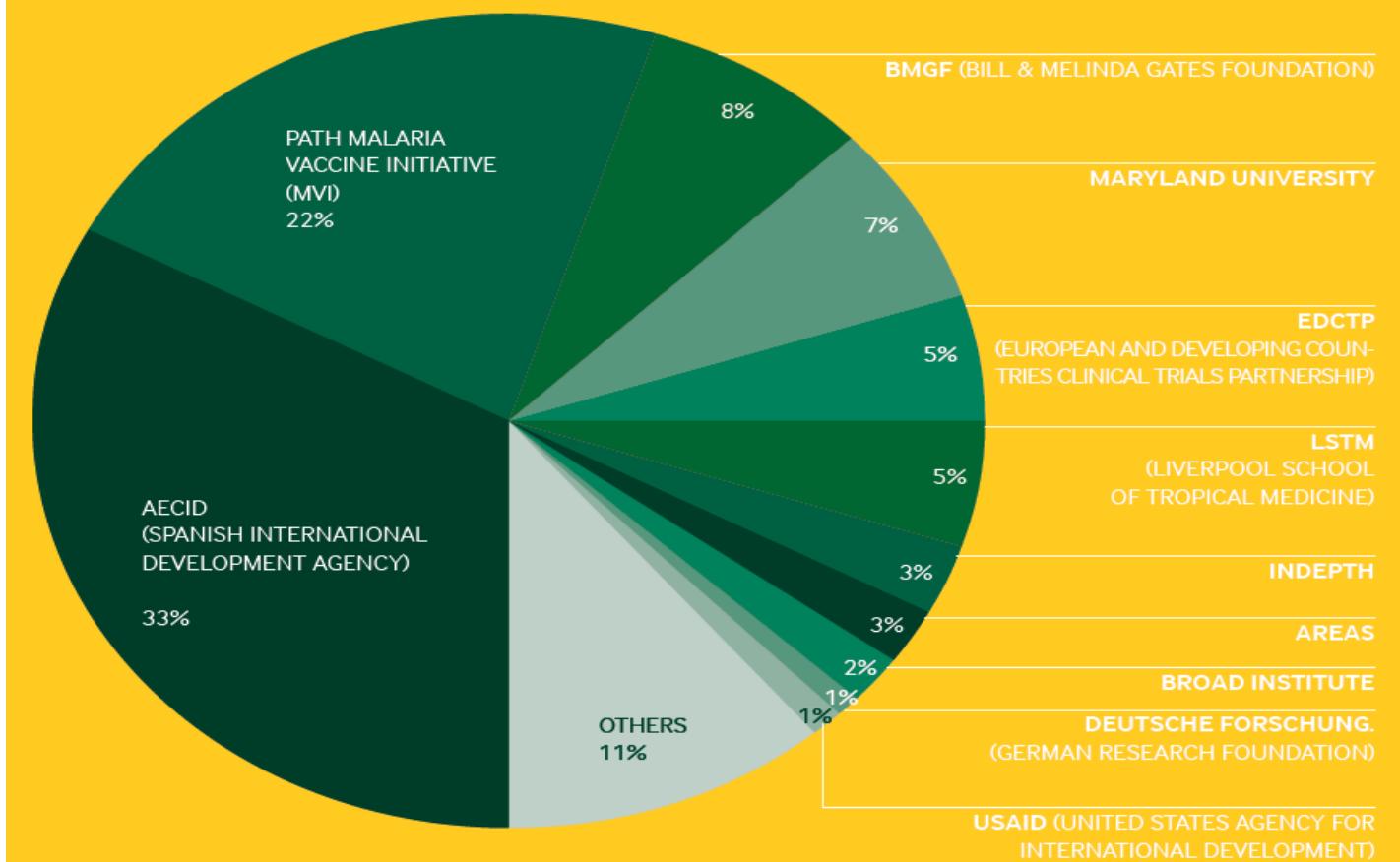
## Administration

- ✓ Salaries (local and expatriate personal)
  
- ✓ Training vs Staff retention



E D C T P

## PRINCIPAIS FINANCIADORES



# 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, Opokuwa Ofori-Anyinam, Margarita M Navia, Sabine Corachan, Marc Ceuppens, Marie-Claude Dubois, Marie-Ange Demoitié, Filip Dubovsky, Clara Menéndez, Nadia Tomieporth, W Ripley Ballou, Ricardo Thompson, Joe Cohen

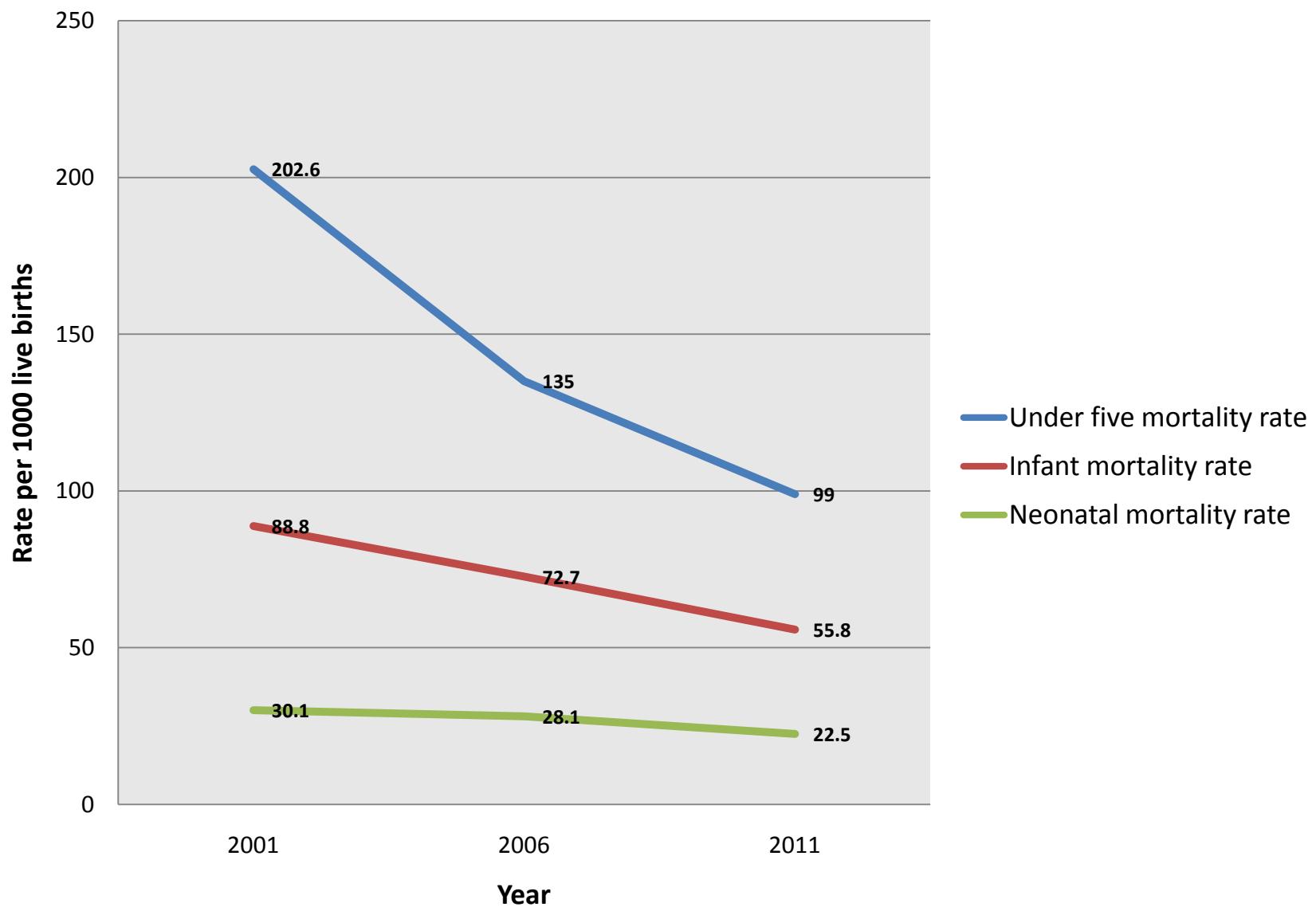
## Intermittent Preventive Treatment for Malaria Control Administered at the Time of Routine Vaccinations in Mozambican Infants: A Randomized, Placebo-Controlled Trial

Eusebio Macete,<sup>1,2</sup> Pedro Aide,<sup>1,3</sup> John J. Aponte,<sup>1,6</sup> Sergi Sanz,<sup>5</sup> Inacio Mandomando,<sup>1,3</sup> Mateu Espasa,<sup>1,6</sup> Betuel Sigauque,<sup>1,3</sup> Carlota Dobato,<sup>5</sup> Samuel Mabunda,<sup>2,4</sup> Martinho DgeDge,<sup>2,5</sup> Pedro Alonso,<sup>1,6</sup> and Clara Menendez<sup>1,6</sup>

<sup>1</sup>Manhiça Health Research Center, Manhiça, and <sup>2</sup>National Directorate of Health, <sup>3</sup>National Institute of Health, <sup>4</sup>National Malaria Control Program, and <sup>5</sup>Community Health Department, Ministry of Health, Maputo, Mozambique; <sup>6</sup>Center for International Health, Hospital Clinic, Institut d'Investigacions Biomèdiques August Pi i Sunyer, University of Barcelona, Spain



# Impact



## **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 développement, Niakhar, Dakar (Senegal)

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- 3 Malaria Research and Training Centre (MRTC), Bancoumana, Bandiagara, Doneguebougou (Mali)
- 4 Centro de Investigação em Saúde da Manhiça (CISM), Manhiça (Mozambique)**
- 5 Bagamoyo/Ifakara Health Research & Development Centre (IHRDC), (Tanzania)
- 6 Medical Research Council (MRC): Basse, Banjul/Fajara, Farafenni (The Gambia)

4 Malaria Institute at Macha, Choma (Zambia)

5 Tropical Diseases Research Centre (TDRC), Ndola (Zambia)

6 Komfo Anokye Teaching Hospital (KATH), Kumasi (Ghana)



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# Building Research Capacity in Africa: Equity and Global Health Collaborations

Kathryn M. Chu<sup>1\*</sup>, Sudha Jayaraman<sup>2</sup>, Patrick Kyamanywa<sup>3</sup>, Georges Ntakiyiruta<sup>3</sup>

<sup>1</sup> Center for Surgery and Public Health, Brigham and Women's Hospital, Harvard Medical School, Department of Surgery, Boston, Massachusetts, United States of America,

<sup>2</sup> Virginia Commonwealth University Medical Center, Department of Surgery, Richmond, Virginia, United States of America, <sup>3</sup> University of Rwanda, School of Medicine, Department of Surgery, Butare, Rwanda

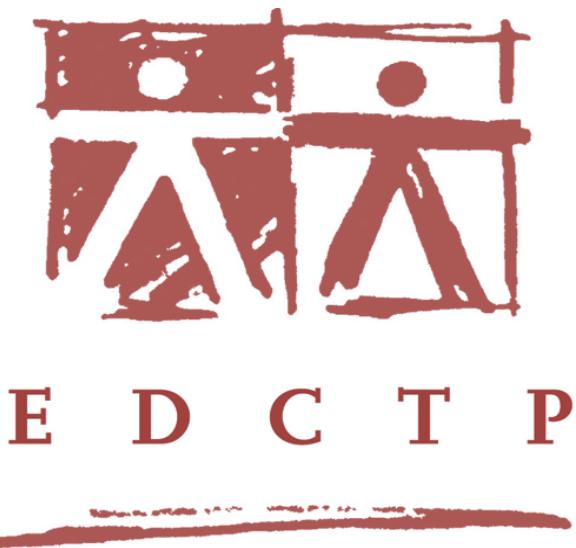
1. How can African institutions and physicians benefit from international research collaborations without being exploited?
2. How can advancement of African research capacity and academic careers be prioritized while satisfying the “publish or perish” mandate of HIC universities?
3. How do African scientists and governments coordinate the great influx of HIC academics who view the continent as the next frontier in global health research?

# Professor fellowship





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