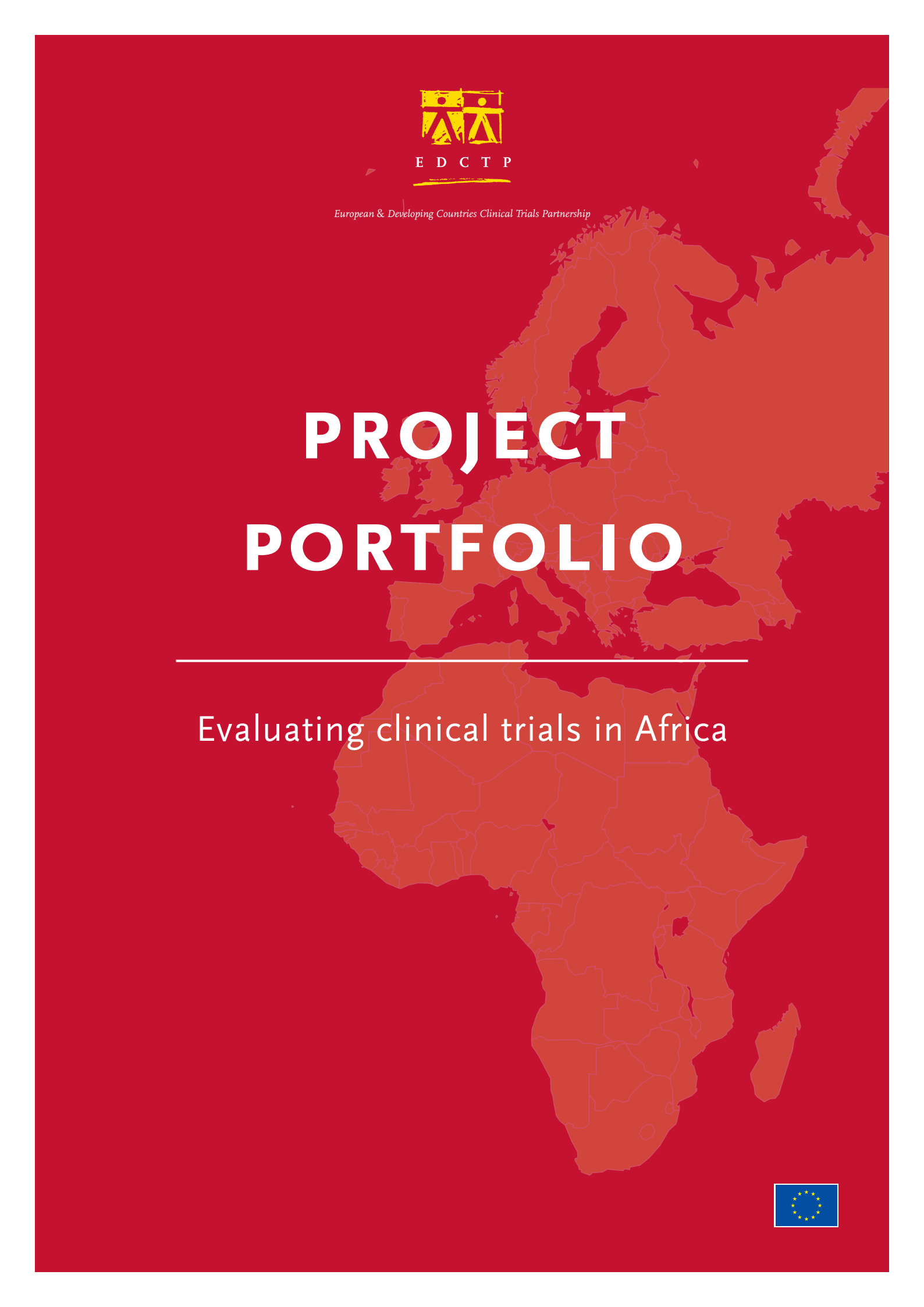
EDCTP

European & Developing Countries Clinical Trials Partnership

PROJECT PORTFOLIO

Evaluating clinical trials in Africa



1 Joint Call by Member States (JCMS)

JCMS 2010 call for 'Evaluating the Impact of Clinical Trials in Africa' supported by EDCTP

Project Acronym (Coordinator)	Health Systems Disease Area	Trials under study	Trial Sites	Status
Munguambe	Malaria/TB	• A phase IIb proof-of-concept efficacy trial of the RTS,S/AS candidate malaria vaccine in children 1 to 4 years in Mozambique, and in infants in Tanzania • A trial of the RTS, S/AS candidate malaria vaccine in newborns in Mozambique and Tanzania • A phase III efficacy trial of the RTS,S malaria vaccine candidate in children aged 5 to 17 months, and infants aged 6 to 12 weeks in Gabon, Tanzania, and Mozambique • Trial to evaluate alternative antimalarial drugs to sulfadoxine-pyrimethamine (SP) for intermittent preventive treatment in pregnancy (IPTp) in the context of insecticide treated nets in Gabon, Tanzania, and Mozambique (EDCTP funded) • Intermittent preventive treatment of malaria in infants (IPTi) with SP in Gabon, Tanzania, and Mozambique • A phase II trial of GMZ2.4 malaria vaccine candidate in children 1-5 years in Gabon • In vivo trial of combination therapy for treatment of malaria in Tanzania • Phase II assessment of TB therapy in Tanzania (EDCTP funded)	1. Mozambique - Manhiça study area, which includes the Manhiça District Hospital and 5 health centres (Maragra, Ilha Josina, Taninga, Malavele, and Palmeira). 2. Tanzania - Bagamoyo and Kisarawe Districts. Bagamoyo District - Bagamoyo District Hospital. 3. Gabon - Ogooué et Lacs District - the Albert Schweitzer District Hospital, the Lambarene Regional District Hospital, the Fougamou Regional Rural Hospital, the Makouke Health care centre and 10 dispensaries.	Ongoing
Pare Toe	Malaria	• Burkina Faso and Zambia: PREGACT (Donor: EDCTP. Status: ongoing) • Multicentre trial "Safe and efficacious artemisinin-based combination treatments for African pregnant women with malaria" (PREGACT, NCT00852423) • Burkina Faso Malactres trial (Funder FP7. Status: completed at the end of 2010) "In vivo and in vitro	1. Burkina Faso – Nanoro: Institut de Recherche en Science de la Santé (IRSS) and Centre Médical avec Antenne chirugicale (CMA). Bobo Dioulasso: IRSS/Centre Muraz and Dafra district hospital. 2. Zambia – Nchelenge district	Ongoing

		efficacy of the recommended first line antimalarial treatments (artemetherlumefantrine and amodiaquine-artesunate) in children with uncomplicated malaria in Burkina Faso" (Malactres, NCT00808951) is carried out in Bobo Dioulasso (Burkina Faso). • Ghana, Study 13-Rectal Artesunate. (Funder WHO/TDR and EU. Status: ended). • Multi-center double-blind randomisedcontrolled trial that evaluated the effect of rectal artesunate on child mortality in the Kassena-Nankana district of northern Ghana.	3. Ghana - Kassena-Nankana district: Navrongo Health Research Center.	
Asante	Malaria	Ghana and Kenya : • Kintampo and Kilifi Malaria Vaccine Trial – phase II efficacy, safety and immunogenicity trial of GSK's RTS,S malaria vaccine with the aim of integrating into routine immunization for infants. • Phase I Safety and immunogenicity of heterologous prime-boost with the candidate malaria vaccines AdCh63 ME-TRAP and MVA ME-TRAP in healthy adults in a malaria endemic area • the phase IIb and malaria drug trials that preceded the RTS,S vaccine Burkina Faso: • Since 2003, CNRFP has conducted three phase I trials among children 12-24 months old and adults 18-40 years respectively. Also as part of an EDCTP funded integrated Project • IP_08_31100 (MVVC) CNRFP will implement a Phase IIb clinical trial entitled "Integrating capacity building and networking in the design and conduct of Phase I and II clinical trials of viral vectored candidate malaria vaccines in East and West African children and infants". This multi-site Phase II trial also involves KEMRI-Kilifi, Kenya. This clinical trial will commence in 2011 and will end in 2013	1. Ghana – Kintampo: Kintampo Health Research Centre 2. Kenya – Kilifi: KEMRI Kilifi 3. Burkina Faso – Ouagadougou: Centre Nacional du Recherche et de formation sur le Paludisme (CNFRP)	Ongoing

1.1 Munguambe

EDCTP Project Coordinator:	Khatia Munguambe (Manhiça Health Research Center, Mozambique)
EDCTP Call Title:	JCMS Evaluating the Impact of Clinical Trials in Africa
EDCTP Project Title:	Evaluating the impact of clinical trials on health services delivered to women and children in three countries (Mozambique, Gabon and Tanzania) of sub-Saharan Africa
EDCTP Project Code:	JC.2010.10300.005
EDCTP Project Start Date:	30 December 2011
EDCTP Project End Date:	29 December 2013
Collaborators:	• Salim Abdulla (Ifakara Health Research and Development Centre, Tanzania) • Selidji Todagbe Agnandji (Albert Schweitzer Hospital, Gabon) • John Aponte (Hospital Clinic of Barcelona, Spain) • Caterina Guinovart (Hospital Clinic of Barcelona, Spain) • Bertrand Lell (Albert Schweitzer Hospital, Gabon) • Elisa Sicuri (Centre de Recerca en Salut Internacional de Barcelona (CRESIB), Spain)
Site Principal Investigator(s):	• Khatia Munguambe (Mozambique) • Salim Abdulla (Tanzania) • Selidji Agnandji (Gabon)
Trial/Study title:	Evaluating the impact of clinical trials on health services delivered to women and children in three countries (Mozambique, Gabon and Tanzania) of sub-Saharan Africa
Goal:	This study aims to understand the influence of clinical trials targeting women and children on healthcare delivered to these population groups in clinical trial sites in 3 sub-Saharan African countries: Mozambique, Tanzania and Gabon
Primary Objective(s):	1. The qualitative indicators will be evaluated through data generated by focus group discussions with community members, and case studies of the above listed clinical trials 2. The quantitative assessment will be done through a community based household survey and a health facility survey.
Clinical Trial/Study site(s):	• Manhiça study area, which includes the Manhiça District Hospital and 5 health centres (Maragra, Ilha Josina, Taninga, Malavele, and Palmeira) where clinical trials are being or have been conducted. The control cluster will include the rest of the district, not covered by DSS, with Xinavane Rural Hospital and 4 other health centres (Munguine, Maluana, Calanga, and 3 de Fevereiro). • Bagamoyo (74 Km North of Dar-es-salaam) and Kisarawe (40 Km South-west of Dar-es-salaam) Districts. The intervention cluster will be Bagamoyo District - Bagamoyo District Hospital. The control cluster will be Kisarawe district, with Kisarawe District hospital and its surrounding dispensaries, where there is no research infrastructure and no ongoing clinical trials. • Lambarené study population: Ogooué et Lacs (250 km from Libreville) and Mouila (580 Km from Libreville). The intervention cluster will be Ogooué et Lacs District - the Albert Schweitzer District Hospital, the Lambarene Regional District Hospital, the Fougamou Regional Rural Hospital, the Makouke Health care centre and 10 dispensaries, all previously and/or currently involved in clinical trials. The

	control cluster will be Mouila District with a population of 15,000.
Collaborating site(s):	• Institute of Tropical Medicine, University of Tuebingen (Germany) • Hospital Clinic of Barcelona CRESIB (Spain)
Study design:	Cross-sectional cluster survey comparing intervention and control groups
Number of subjects:	There will be a total of 6 clusters: one intervention and one control cluster per site.
Cofunders:	NACCAP (Netherlands) ISCIII (Spain) University of Teubingen (Germany)
Status:	Ongoing
Results and Outcomes:	Quantitative and qualitative studies have both started at all sites.

1.2 Pare Toe

EDCTP Project Coordinator:	Léa Pare Toé (Centre Muraz, Burkina Faso)
EDCTP Call Title:	JCMS Evaluating the Impact of Clinical Trials in Africa
EDCTP Project Title:	Impact of clinical trials on the health behaviours of the communities and the quality of the health services in West and South Africa (Burkina Faso, Ghana and Zambia)
EDCTP Project Code:	JC.2010.10300.008
EDCTP Project Start Date:	4 October 2011
EDCTP Project End Date:	3 August 2013
Collaborators:	• James Akazili Ghana (Navrongo Health Research Centre, Ghana) • Frank Baiden (Kintampo Health Research Center, Ghana) • Victor Chalwe (Tropical Diseases Research Centre, Zambia) • Umberto D'Alessandro (Prince Leopold Institute of Tropical Medicine (ITM), Belgium) • K. Maxime Drabo (Centre Muraz, Burkina Faso) • Derrick Elemu (University of Zambia (UNZA), Zambia) • Abraham Hodgson (Navrongo Health Research Centre, Ghana) • Koen (Peeters ITM, Belgium) • Rafaella Ravinetto (ITM, Belgium) • Nancy Soko (Tropical Diseases Research Centre, Zambia) • Halidou Tinto (Centre Muraz, Burkina Faso)
Site Principal Investigator(s):	• Lea Pare Toe (Burkina Faso) • Victor Chalwe (Zambia) • Abraham Hodgson (Ghana)
Trial/Study title:	Impact of clinical trials on the health behaviours of the communities and the quality of the health services in West and South Africa (Burkina Faso, Ghana and Zambia)
Goal:	Carry out a comprehensive evaluation of the impact of public health oriented clinical trials on local communities and the corresponding health system. To achieve this, the project will address the following research questions: Does the implementation of clinical trials have an impact on access to care and health facility utilization, i.e. frequency of attendance, early attendance or delay, increased/decreased trust, etc? In case of positive changes, can these be maintained over time and beyond the presence of the research team? If negative or no changes, is there anything that could be done to improve the situation? What is the impact on health staff and health services in terms of: quality of care for all patients; skills and motivation of the health staff; other possible factors of change. Is there any indirect benefit (development of trade, employment or local infrastructure) related to the implementation of the trials, and if yes, can these be maintained?
Primary Objective(s):	• To analyse the impact of clinical trials on the quality of care and the community's health behaviour • To describe the skills and motivation of the health staff in the context of clinical trial implementation versus the context of no clinical trial • To describe the quality of care for all patients in the context of clinical trial implementation versus the context of no clinical trial • To analyse patients' and communities' perception of the various benefits and constraints of participation in clinical trials (e.g., free care, loss of time, reimbursements, home visit by health workers, risks of participating)

	• To analyse changes in the patterns of individual/family care seeking (medical, traditional, consultation of various health providers, etc.) during and after a clinical trial.
Clinical Trial/Study site(s):	• Institut de Recherche en Science de la Santé (IRSS) and Centre Médical avec Antenne, Nanoro (Burkina Fasp) chirugicale (CMA). Bobo Dioulasso: IRSS/Centre Muraz and Dafra district hospital • Tropical Diseases Research Centre Ndola and University of Zambia, Lusaka, Nchelenge district (Zambia) • Kintampo Health Research Center and Navrongo Health Research Center, Kassena-Nankana district (Ghana).
Collaborating site(s):	Institute of Tropical medicine Prince Leopold (Belgium)
Study design:	Quantative and qualitative data analysis
Cofunders:	NACCAP (Netherlands) SIDA (Sweden)
Status:	Ongoing
Results and Outcomes:	All qualitative surveys were completed with in total 141 interviews realised in Ghana, 221 in Zambia and 333 in Burkina Faso. The quantitative surveys are ongoing in all three countries.

1.3 Asante

EDCTP Project Coordinator:	Kwaku Poku Asante (Kintampo Health Research Center, Ghana)
EDCTP Call Title:	JCMS Evaluating the Impact of Clinical Trials in Africa
EDCTP Project Title:	An evaluation of the impact of malaria clinical trials on the delivery of health care, particularly for women and children, in sub-Saharan Africa
EDCTP Project Code:	JC.2010.10300.009
EDCTP Project Start Date:	27 October 2011
EDCTP Project End Date:	26 April 2013
Collaborators:	• Traore Abdoulaye (Centre national de recherche de Formation sur le Paludisme (CNRFP), Burkina Faso) • Bright Akpalu (Kintampo Health Research Center, Ghana) • Konate Amadou Tidiana (CNRFP, Burkina Faso) • Yaro Jean-Baptiste Bibié (CNRFP, Burkina Faso) • Daniel Chandramohan (London School of Hygiene and Tropical Medicine (LSHTM), UK) • Roma Chilengi (African Malaria Network Trust, Tanzania) • Lawrence Gyabaa Febir (Kintampo Health Research Center, Ghana) • Egeruan Babatunde Imoukhuede (European Vaccine Initiative (EVI), Germany) • Caroline Jones (Kenya Medical Research Institute (KEMRI), Kenya) • Malick Lankoandé (CNRFP, Burkina Faso) • Deborah Mogaka (KEMRI, Kenya) • Sassy Molyneux (KEMRI, Kenya) • Issa Ouedraogo Nebie (CNRFP, Burkina Faso) • Seth Owusu-Agyei (Kintampo Health Research Center, Ghana) • Benjamin Sombie (CNRFP, Burkina Faso) • Charlotte Tawiah-Agyemang (Kintampo Health Research Center, Ghana) • Alfred Tiono (CNRFP, Burkina Faso) • Jayne Webster (LSHTM, UK)
Site Principal Investigator(s):	• KP Asante (Ghana) • Roma Chilengi (Kenya) • Amadou Tidiana (Burkina Faso) • Alfred Tiono (Burkina Faso)
Trial/Study title:	An evaluation of the impact of malaria clinical trials on the delivery of health care, particularly for women and children, in sub-Saharan Africa.
Goal:	The study is designed to assess the impact of clinical trials on the communities and facilities where they are conducted, with emphasis on the impact on women and children.
Primary Objective(s):	The proposed research seeks to address the following principal questions: 1. What is the range of inputs (infrastructural and human resource capacity) that malaria clinical trials bring to trial centres in SSA? 2. What are the expectations and perceptions among health providers, community members, public health service providers, and policy makers of the impacts of clinical trials especially on health services provided for women and children; and specifically with regard to: 1) delivery of routine health care 2) quality of care 3) policy change? 3. What are the key factors that limit or enhance positive and negatives impacts associated with trials (e.g. local and international regulations, type of trial, type of

	implementing institution, level of embeddedness in health systems, nature of the local health system, community engagement strategy, perceptions of the key stakeholders etc)? 4. What are the ways in which clinical trials in SSA are embedded within health facilities and wider health systems and the perceptions of key stakeholders such as health service providers, researchers and policy makers on the different approaches taken? 5. Do the range of inputs, perceptions of community and key health stakeholders, and impacts of clinical trials in SSA change over the life of the trial and in post-trial contexts, and why?
Clinical Trial/Study site(s):	• Kintampo Health Research Centre (Ghana) • KEMRI – Kilifi (Kenya) • Centre National de Recherche et de Formation sur le Paludisme, Ouagadougou (Burkina Faso)
Collaborating site(s):	• London School of Hygiene and Tropical Medicine (UK) • KEMRI-Wellcome Trust Research Programme (UK) • European Vaccine Initiative (Germany)
Study design:	Quantative and qualitative data analysis
Cofunders:	• NACCAP (Netherlands) • SIDA (Sweden) • MRC (UK)
Status:	Ongoing
Results and Outcomes:	Qualitative data collection has started and ongoing in Kintampo; data collection is pending in CNRFP and KEMRI Kilifi.
Publications:	