EDCTP

European & Developing Countries Clinical Trials Partnership

PROJECT PORTFOLIO

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1 Member States Initiated projects

Member states initiated projects in HIV/AIDS, tuberculosis, and malaria capacity building and networking projects supported by EDCTP. Details of individual projects can be found in the sections on HIV/AIDS, tuberculosis, capacity building and networking projects.

Project Acronym (Coordinator)	Phase of trial	Product(s)	Manufacturer / Developer	Study population	Status
Fomsgaard MSI-HIV vaccine (Fomsgaard)	I	HIV vaccine peptide and CAF01 adjuvant	SSI	Untreated healthy individuals with chronic HIV-1 N=23	Completed
Strub-Wourgaft - Malaria Treatment (Strub Wourgaft)	IV	Artesunate Mefloquine (ASMQ) Artemether – Lumefantrine (Coartem®)	Cardinal Systems	Young children who are particularly at risk of malaria. N=940	Ongoing
FATI (Hoelscher)	IIa	Fozivudine	Chiracon	Adults (male and female), ≥ 18 years of age, HIV-1 positive, ATR naïve, n = 75 participants both in Mbeya, Tanzania and Abidjan, Côte d'Ivoire sites.	Ongoing
TBTEA (Kaufmann)	n/a	n/a	n/a	n/a	Ongoing
WANETAM PLUS (Jaye)	n/a	n/a	n/a	n/a	Ongoing
quinACT (Van Geertruyden)	III	Artemether-lumefantrine combination (Coartem®) ; Artesunate-Amodiaquine combination (Co-arsucam®) ; Quinine (Quinimax®)/Sanofi-Aventis + Clindamycin (Dalacin®)	Novartis, Sanofi-Aventis, Pfizer	1800 children per site (Democratic Republic of Congo and Uganda) between 6 and 59 months with non-severe malaria	Ongoing
Kreidenweiss	n/a	n/a	n/a	n/a	Ongoing
XACT (Dheda)	n/a	Urine LAM lateral flow strip test (Determine TB®) GeneXpert	Inverness Medical Professional Diagnostics Cepheid, Sunnyvale, California USA	Adults (≥18 years old) HIV positive and negative N = 400 per site	Ongoing

Project Acronym (Coordinator)	Capacity Building Goal	Study population	Status of project
Fomsgaard MSI-HIV vaccine (Fomsgaard)	• To sustain healthy and HIV-I infected cohorts in the Republic of Guinea-Bissau (RGB) in preparation for HIV AIDS vaccine trials. • To transfer sustainable HIV AIDS clinical-trial capacity, technology, infrastructure, knowledge and expertise from four countries (Denmark, the UK, The Gambia and Senegal) to the Republic of Guinea-Bissau. • To compare the safety and immunogenicity of an lipid-adjuvanted, CTL-epitope based HIV vaccine in two distinct populations, one living in Denmark and the other one living in Guinea-Bissau.	n/a	Completed
Magesa MSI-Malaria Capacity Building (Magesa)	• To build capacity for research management • To build capacity for laboratory support of clinical trials. Hospital through the construction of a research laboratory • To improve networking and to create a scientific forum for Tanzanian and European Researchers • To improve capacity of junior staff to participate in clinical research	n/a	Ongoing
FATI (Hoelscher)	• The design and conduct of an EMA compliant phase II clinical trial with 4 different doses of Fozivudine in comparison with the standard AZT containing regimen. • A rational for selecting the appropriate doses to be carried forward in more advanced clinical development • The continuation of ongoing upgrades of clinical and research infrastructure as well as equipment and laboratory infrastructure will allow future expansion of the HIV related monitoring lab facilities in Mbeya, Kumasi and Abidjan • Promote direct interaction between the five African study sites and European partner institutions to facilitate sharing of expertise and intellectual resources needed for implementation and successful completion of HIV drug trials.	Adults (male and female), ≥ 18 years of age, HIV-1 positive, ATR naïve, n = 75 participants both in Mbeya, Tanzania and Abidjan, Côte d'Ivoire sites.	Ongoing
TBTEA (Kaufmann)	• Through sharing and exchanging of scientific, technological, clinical and infrastructural know-how and practical experiences between all involved European and African partners on the following clinical interactions, SSI-AHRI (H1/IC31), UOXF-SATVI and UOXF-LEDANTEC (MVA85A), and MPIIB-SUN (VPM1002). This will stimulated in a joint workshop (networking work package) and short term training of technical and laboratory staff with specific emphasis on novel and existing clinical assays. • Through early and timely exchange of know-how and technology transfer between UNIZAR (MTBVAC) and INSERM (HBHA) with prospective African	n/a	Completed

	partners, to prepare and build (specific) capacity for future clinical trials on MTBVAC and HBHA. This will be stimulated through short term training and exchange visits of post doc fellows to the clinical sites. • Through continuous north-north, north-south and south-south exchange and transfer of knowledge and technologies by Post docs, Students and PhDs on current, and novel or improved assays for clinical evaluation of immune responses towards all these vaccines, specifically regarding multi-parameter FACS based assays, HBHA-IGRA, and Mycobacterial Growth Inhibition Assays (MGIAs).		
WANETAM PLUS (Jaye)	• Establishment of links with the newly formed BE-supported TB network and the West African Platform for HIV Intervention Research • Involvement of new partners for TB and malaria • A practical GCP course co-developed by Dr. Halidou Tinto at the Clinical Research Unit Malaria in Nanoro (Burkina Faso) and Prof. Umberto d'Alessandro, with the support of the Clinical Trials Unit (Raffaella Ravinetto) at ITM • A course in biomedical engineering at the MRC Gambia • A course in laboratory management at the MRC Gambia • English language training at the MRC Gambia • Four Masters/ short course equivalents at the ITM in Antwerp • Hands-on TB training on second line drug resistance testing in Antwerp • Hands-on training on P. falciparum genotyping related to clinical trials in Antwerp in year 1, followed by transfer of this training to The Gambia • Two scholarships per year for WANETAM plus members to attend the annual Diplome Universitaire laboratory science course organized by Prof. Mboup in Dakar • A network meeting with workshop on "clinical research in Africa with specific attention to ethical issues" • Strengthening of the WANETAM website	n/a	Ongoing
quinACT (Van Geertruyden)	• To determine the safety and efficacy of 2 ACTs (ASAQ and AL) vs quinine when administered to children under five with recurrent P. falciparum infection and to collect explanatory variables for treatment failure (PCRcorrected) and for recurrent parasitaemia. • To develop disease-endemic country (DEC) research capacity through training and professional development of scientists, building of infrastructure and transfer of technology. • To coordinate research efforts on treatment and prevention tools of malaria in children and, by doing so, finalise a common research agenda and promote the rational use of available resources.	1800 children per site, between 6 and 59 months with non-severe malaria.	Ongoing

Kreidenweiss	• To develop an assay for detection of multiple parasitic infections during pregnancy including potentially cryptic placental *Plasmodium falciparum*. This is based on the joint expertise of the German and the French research projects where the Germans bring in the microbead platform for simultaneous parasite detection and the French their competence in pregnancy-associated malaria. • The investigators intend to do this work in frame of capacity building activities of African scientists to enable African institutions performing high-level research which is competitive amongst the international malaria research community. • Amongst the 3 collaborators the activities will harmonize research procedures and techniques and ensure further effective collaborations in the development of cutting edge diagnostic technologies for controlling malaria.	n/a	Ongoing
XACT (Dheda)	• XACT has 3 main streams of capacity development. These are: (i) the training of students through sponsorhip of studies and the research activity that forms part of their projects, (ii) the development of infrastructure for support future research, and (iii) the training of personnel through courses. The proposed project will be conducted in the community as a mobile health unit. However, symptomatic persons will be taken to the local clinic where considerable site infrastructure has already been developed through the TB-Susgent (EU FP7-funded), TB-Neat (EDCTP-funded), and TESA (EDCTP-funded) projects. The designated clinics in Harare and Cape Town have already been extended and upgraded, have had Gene Xpert machines installed, infection control measures and other facilities have been established in order to undertake the clinical trials, including communication infrastructure, etc. Thus, there is considerable interaction between the different studies and the foundations and infrastructure setup through the EDCTP-funded and EU FP7-funded projects are now being utilised here to create a multiplier effect.	400 per site (N = 1200)	Ongoing

1.1 Fomsgaard AFO-18

EDCTP Project Coordinator:	Anders Fomsgaard (Statens Serum Institut, (SSI), Denmark)
EDCTP Call Title:	Call for the support of member states initiated projects within the scope of EDCTP activity areas
EDCTP Project Title:	A joint initiative to sustain HIV vaccine trials and research capacity in the Republic of Guinea-Bissau, West Africa
EDCTP Project Code:	MS.09.10800.001
EDCTP Project Start Date:	27 July 2010
EDCTP Project End Date:	26 July 2012
Collaborating partners:	• Peter Aaby (Bandim Health Project, Guinea-Bissau) • David Da Silva Te (Hospital Nacional Simao Mendes, Guinea-Bissau) • Vibeke Fonsholt (SSI, Denmark) • Victor Gomes (Bandim Health Project, Guinea-Bissau) • Tomas Hanke (University of Oxford, UK) • Assan Jaye (Medical Research Council (MRC) Laboratories, The Gambia) • Skov Sanne Jensen (SSI, Denmark) • Kristoffer Jarlov Jensen (SSI, Denmark) • Zacarias José da Silva (National Public Health Laboratory NPHL, Guinea-Bissau) • Gitte Kronborg (Hvidovre University Hospital, Denmark) • Souleymane Mboup (University Cheikh Anta DIOP de Dakar (UCAD), Senegal) • Candida Medina Rodrigues (ospital Nacional Simao Mendes, Guinea-Bissau) • Amabelia Rodrigues (SSI, Denmark)
Clinical Trial	
Site Principal Investigator(s):	David de Silva Te (National HIV secretariat, Ministry of Health, Guinea Bissau) Anders Fomsgaard (Statens Serum Institutet)
Clinical Trial/Study Sponsor:	Statens Serum Institut (Denmark)
Trial/Study title:	HIV-1 Peptide immunisational individuals in West Africa to prevent disease (AFO-18)
Goal:	Evaluate the safety and tolerability of the vaccine and the immunological and anti-retroviral response in vaccinated individuals
Primary Objective(s):	Evaluate the safety and tolerability of the vaccine
Secondary Objective(s):	Determine whether vaccine with the selected epitope antigens can induce a measurable specific immune response to the patient's HIV-1 when used during chronic HIV-1 infection and to evaluate the clinical effect measured as induction of new T-cell immune response, lowering of viral load, and increase in the CD4 cell count.
Third Objective	Evaluate the feasibility of conducting an HIV immunisation study in a poorly resourced African setting
Clinical Trial/Study site(s):	• Projecto de Saúde de Bandim (Guinea-Bissau) • Clinica Tratamento Antiretrovirais, Hospital Nacional Simão Mendes (Guinea-Bissau) • Laboratório Nacional de Saúde Pública (LNSP, Guinea-Bissau)
Collaborating site(s):	• Simão Mendes Hospital Céu e Terra (Guinnea-Bissau) • Laboratoire de Bacteriologie Virologie, Université Cheikh Anta DIOP (Senegal) • Immunology Section, Viral Diseases Programme, MRC Fajara

	Laboratories (The Gambia) • Department of Virology, SSI (Denmark)
Study design:	Single-Blinded, placebo-controlled phase I trial
Product(s):	cationic liposome-adjuvanted CAF01 HIV-1 peptide vaccine (AFO-18)
Manufacturer/Developer:	SSI (Denmark)
Cofunders	• Danish International Development Agency, Denmark (DANIDA) • Medical Research Council UK, UK (MRC UK)
Trial Registration number(s):	• PACTR 201110000274327 • NCT 01009762 • NCT 01141205 (DK study)
Status:	Completed
Results and Outcomes:	Following vaccine testing on similar HIV positive individuals first in Copenhagen (approved and followed by Danish Medicine Association, Ethical committee, etc), the study started in Guinea-Bissau in August 2010. Recruitment in RGB was completed with a total of 23 patients (18 vaccinees and 5 placebos).Trial was completed in September 2011 and follow up in December 2011. There were two drop-outs and one non-vaccine-related serious adverse event in the vaccine treatment arm. In the placebo treatment arm there was one dropout and one non-vaccine-related serious adverse event. Thus a total of 18 participants completed the six-month follow-up (15 vaccinees as planned and 3 placebos). Immunization with peptides in the new adjuvant CAF01 induced T-cell responses to epitopes previously undetected in 6/14 vaccinated individuals. The immunizations were safe and well tolerated albeit with no significant changes in HIV-1 viral load or CD4 T-cell counts.
Capacity Building	
Site Principal Investigator(s):	Amabelia Rodrigues (Denmark) Christoph Janitzek (Denmark)
Clinical Trial/Study Sponsor:	SSI (Denmark)
Goal:	• To transfer sustainable HIV/ AIDS clinical -trial capacity, technology, infrastructure, knowledge and expertise from four countries (Denmark, the UK, The Gambia and Senegal) to the Republic of Guinea-Bissau. • To sustain healthy and HIV-1 infected cohorts in the Republic of Guinea-Bissau in preparation for HIV/AIDS vaccine trials
Primary Objective(s):	Introduce and maintain haematology and clinical chemistry and viral and immunology techniques
Secondary Objective(s):	Train key personnel in English and GCP
Clinical Trial/Study site(s):	• Projecto de Saúde de Bandim (Guinea-Bissau) • Clinica Tratamento Antiretrovirais, Hospital Nacional Simão Mendes (Guinea-Bissau) • Laboratório Nacional de Saúde Pública (LNSP, Guinea-Bissau)
Collaborating site(s):	• The John Radcliffe MRC Human Immunology Unit, University of Oxford (UK) • Projecto de Saúde de Bandim (Guinea-Bissau) • Clinica Tratamento Antiretrovirais, Hospital Nacional Simão Mendes (Guinea-Bissau) • Laboratório Nacional de Saúde Pública (LNSP, Guinea-Bissau) • Laboratoire de Bacteriologie Virologie, Université Cheikh Anta DIOP (Senegal) • Immunology Section, Viral Diseases Programme, MRC

	Laboratories (The Gambia) • Department of Virology, SSI (Denmark)
Total number of subjects (cohort/epidemiological/ other studies):	Cohort: app 300 HIV-1 positive healthy individuals
Cofunders	• Danish International Development Agency (DANIDA, Denmark) • Medical Research Council UK, UK (MRC UK)
MSc studies:	Title: MSc Biology - Biotechnology HIV-1 subtypes in Republic of Guinea Bissau Candidate: Sanne Skov Jensen (University of Copenhagen, Denmark) Completed: 2011 - June 2011
	Title: LSHTM long-distance course MSc Clinical Trials under Candidate: Delfim Vicente Mendes (Hospital Rauol Follereau, Guinnea-Bissau) Completed: 2010 - June 2012
Results and Outcomes:	The capacity building efforts that have come to fruition through the project's "learning-by-doing" approach have been substantial. Primarily achieving the objective of providing courses in GCP and Research Ethics in three languages, English-language training, enrolment of a local Medical Doctor to a MSc online course and building a molecular biology and serology platform in Bissau in preparation for future clinical trials in the region. The project has also introduced and sustained new laboratory techniques (molecular virology and testing of patients for CD4 counts, viral-load, haematology/clinical chemistry parameters. In terms of networking, the project enabled the setting up and definition of a new African network involving The Gambia and Senegal via WAPHIR for continued support of the capacity building programme initiated through this EDCTP grant. Lastly, the project used innovative methods such as documentaries and TV interviews to communicate research and public health projects in the region.
Publications:	1. Fomsgaard A, Karlsson I, Gram G, Schou C, Tang S, Bang P, Kromann I, Andersen P, Andreasen LV. Development and preclinical safety evaluation of a new therapeutic HIV-1 vaccine based on 18 T-cell minimal epitope peptides applying a novel cationic adjuvant CAF01. *Vaccine*. 2011 Sep 16;29(40):7067-74. Epub 2011 Jul 19 2. Karlsson I, Kløverpris H, Jensen KJ, Stryhn A, Buus S, Karlsson A, Vinner L, Goulder P, Fomsgaard A. Identification of Conserved Subdominant HIV Type 1 CD8(+) T Cell Epitopes Restricted Within Common HLA Supertypes for Therapeutic HIV Type 1 Vaccines. *AIDS Res Hum Retroviruses*. 2012 Nov;28(11):1434-43. doi: 10.1089/AID.2012.0081. Epub 2012 Aug 14. 3. Karlsson I, Brandt L, Vinner L, Kromann I, Andreasen LV, Andersen P, Gerstoft J, Kronborg G, Fomsgaard A. Adjuvanted HLA-supertype restricted subdominant peptides induce new T-cell immunity during untreated HIV-1-infection. *Clin Immunol*. 2013 Feb;146(2):120-30. doi: 10.1016/j.clim.2012.12.005. Epub 2012 Dec 21. 4. Gómez Román VR, Skov Jensen S, Leo-Hansen C, Jarlov Jensen K, Janitzek CM, Medina Rodrigues C, Jespersen S,

	Katzenstein TL, da Silva Té D, Fomsgaard A. Assessing HIV-1 patient recruitability in Guinea-Bissau: African versus North-American haematology and biochemistry reference intervals. *Clin Vaccine Immunol*. 2012 Aug;19(8):1322-5. Epub 2012 Jun 6 5. Jensen KJ, Gómez Román VR, Jensen SS, Leo-Hansen C, Karlsson I, Katzenstein TL, Rodrigues CM, Jespersen S, Janitzek CM, Té Dda S, Hayes P, Fomsgaard A. Clade A HIV-1 Gag-specific T cell responses are frequent but do not correlate with lower viral loads in a cohort of treatment-naïve HIV-infected individuals living in Guinea-Bissau. *Clin Vaccine Immunol*. 2012 Dec;19(12):1999-2001. doi: 10.1128/CVI.00399-12. Epub 2012 Oct 17.

1.2 Magesa MSI-Malaria Capacity Building

EDCTP Project Coordinator:	Stephen Magesa (National Institute for Medical Research (NIMR), Tanzania)
EDCTP Call Title:	Call for the support of member states initiated projects within the scope of EDCTP activity areas
EDCTP Project Title:	Capacity and network strengthening measures within the framework of malaria research in Tanzania by the Joint Malaria Programme (JMP)
EDCTP Project Code:	MS.09.10800.002
EDCTP Project Start Date:	29 July 2010
EDCTP Project End Date:	28 January 2014
Collaborating partners:	• Adrian Luty (Radboud University Nijmegen, Netherlands) • Raimos Olomi (Kilimanjaro Christian Medical Centre (KCMC), Tanzania) • Hugh Reyburn (KCMC, Tanzania) • Thor Theander (University of Copenhagen, Denmark)
Capacity Building	
Site Principal Investigator(s):	Stephen Magesa (Tanzania)
Goal:	1. To build capacity for research management. The JMP Secretariat will be strengthened through provision of salary support for the JMP Manager and an Assistant, upgrading of office furniture and equipment and transport costs to support training and supervision visits to research project sites. The primary outcomes will be the integration of high quality accounts packages, establishing regular internal audit and standardising a high quality human resource management system through JMP. 2. To build capacity for laboratory support of clinical trials. To strengthen the infrastructure for clinical trials at Teule Hospital through the refubrishment of a research laboratory. The facility will meet the exacting demands of GCLP and external quality assurance to international standards. 3. To improve networking and to create a scientific forum for Tanzanian and European Researchers. To hold an annual scientific meeting for JMP projects to report results to important stakeholders including the National Malaria Control Programme, the Ministry of Health and health service providers. In addition there will be meetings specifically directed to new proposals from young Tanzanian scientists and a one-week proposal writing workshop will be linked at the end of the scientific meeting. 4. To improve capacity of junior staff to participate in clinical research through provision of regular short courses on GCP, good laboratory practice, clinical research ethics, biosafety with certification for qualifying staff in order to improve the quality of research. In addition short courses will be run on research administration and financial management.
Collaborating site(s):	• LSHTM (UK) • University of Copenhagen m(Denmark) • NIMR (Tanzania) • Kilimanjaro Christian Medial College (KCMC, Tanzania) • Radboud University of Nijmegen (Netherlands)
Cofunders	• DANIDA (Denmark)

	• ACT Consortium (UK) (funding via Bill and Melina Gates Foundation) • LSHTM (UK) • FEAST Imperial College London (UK) • NACCAP (Netherlands)
Status:	Ongoing
Results and Outcomes:	The project has improved their ties with the National Ethical Review Board and other regulatory authorities. They participated in the malaria symposium session at the 26th NIMR Annual Joint Scientific Conference held in April 2012 in Arusha, Tanzania as well as the Sixth EDCTP Forum held in Addis Ababa, Ethiopia. In terms of training, two courses on GCP were conducted in January and May 2012 and 68 participants were trained. The 11th JMP annual workshop was successfully held in November 2011. The project has launched the programme website under www.jmp.or.tz to further local and global networking. The necessary office space and infrastructure upgrades have been made at the JMP Secretariat in addition to the grant providing for the personnel costs. Ward refurbishment and upgrade of data management tools at the Teule site were completed in October 2011. As part of laboratory refurbishment and upgrade we procured humidifier and humidistat, microscopes and centrifuge machines, desktops and related accessories and office furniture.

1.3 Strub-Wourgaft - Malaria Treatment

EDCTP Project Coordinator:	Nathalie Strub-Wourgaft (Drugs for Neglected Diseases Initiative (DNDi), Switzerland)
EDCTP Call Title:	Call for the support of member states initiated projects within the scope of EDCTP activity areas
EDCTP Project Title:	Assessment of the fixed-dose combination of Artesunate Mefloquine (ASMQ) as an alternative antimalarial treatment for children in Africa
EDCTP Project Code:	MS.09.10800.004
EDCTP Project Start Date:	16 August 2010
EDCTP Project End Date:	30 April 2014
Collaborating parties:	• Gwenaelle Carn (DNDi, Switzerland) • Ylana Chalem (Cardinal Systems, France) • Laurent Decosterd (Centre Hospitalier Universitaire Vaudois (CHUV), Switzerland) • Zakayo Mrango (National Institute for Medical Research (NIMR), Tanzania) • Michel Vaillant (Centre de Recherche Public de la Santé, Luzembourg) • Laurence Vielfaure (DNDi, Switzerland)
Clinical Trial	
Site Principal Investigator(s):	• Zakayo Mrango (NIMR, Tanzania) • Ali Mtoro (IHI, Tanzania) • John Lusingu (NIMR, Tanzania) • Bernhards OGUTU (KEMRI, Kenya) • Sodiomon Sirima (CNRFP, Burkina Faso)
Clinical Trial/Study Sponsor:	DNDi (Switzerland)
Trial/Study title:	Efficacy, Safety and Population-Pharmacokinetics of Artesunate-Mefloquine combination for the Treatment of Uncomplicated Falciparum Malaria in African children versus Artemether-Lumefantrine
Goal:	To compare the efficacy and safety of the fixed-dose combination of ASMQ with AM-LM in children under the age of five with uncomplicated falciparum malaria in Africa.
Primary Objective(s):	To evaluate efficacy of Artesunate-Mefloquine fixed-dose by determining the proportion of patients achieving a negative parasitaemia without recrudescence by 63 days.
Secondary Objective(s):	1. To measure the parasite reduction ratio on Day 1, 2 and 3 2. To compare the proportion of patients with parasitaemia on Day 2 and 3 3. To compare the proportion of patients with fever on Day 2 and 3 4. To compare the gametocyte carriage at Day 2 and 3, and Day 28, 42 and 63 5. To evaluate cure rate at 28 and 42 days 6. To evaluate the population-pharmacokinetics of Artesunate-Mefloquine in under-5 children 7. To evaluate the incidence and severity of adverse events 8. To evaluate the incidence of Serious Adverse Events and adverse events leading to treatment discontinuation 9. To analyze the discrepancy of time course and vomiting frequency
Clinical Trial/Study site(s):	• Kilosa District Hospital, National Institute for Medical Research (NIMR, Tanzania) • NIMR in Korogwe, Tanzania Ikakara Health Institute (IHI) in

	Bagamoyo (Tanzania) • Ahero District Hospital Kisumu (KEMRI, Kenya) • Balonghin and Banfora District Hospitals (CNRFP, Burkina Faso)
Collaborating site(s):	• National Institute for Medical Research (Tanzania) • Kenya Medical Research Institute (Kenya) • Centre National de Recherche et de Formation sur le Paludisme (Burkina Faso) • CHUV Lausanne (Switzerland) • Cardinal Systems (France) • Centre de Recherche Public – Santé (Luxembourg)
Study design:	Phase IV randomised, controlled, multicentre efficacy and safety study
Total number of subjects:	CHILDREN (≤5 years) children with uncomplicated falciparum malaria N=940
Product(s):	• Artesunate Mefloquine (ASMQ) • Artemether – Lumefantrine (Coartem®)
Manufacturer/Developer:	Farmanguhinos (Brazil) and Cipla (India)
Cofunders	• United Kingdom Department for International Development (DFID) • Netherlands Ministry of Foreign Affairs (DGIS) • ARPE Foundation (Switzerland) • French Development Agency (AFD) for the extension period
Status:	Ongoing
Results and Outcomes:	The trial has completed recruitment of 945 subjects as of 26 June 2013. Burkina Faso : 390 patients Kenya: 347 patients Tanzania :208 patients There were 21 SAE reported during the period: – 7 severe malaria – 6 pneumonia – 3 severe anaemia – 3 malaria – 1 tonsilitis – 1 burns Last monitoring visits were performed in July 2013 in Burkina Faso and August 2013 in Tanzania and Kenya. Database lock expected in Q1 2014.
Trial Registration number(s):	PACTR 201202000278282 ISRCTN 17472707

1.4 FATI

EDCTP Project Coordinator:	Michael Hoelscher (Ludwig-Maximilians Universitat Munchen, Germany)
EDCTP Call Title:	Call for the support of member states initiated projects within the scope of EDCTP activity areas
EDCTP Project Title:	FATI-1: A prospective, multicenter Phase 2a trial to confirm a sustained virological suppression defined as HIV-RNA <50 copies/ml of 4 different doses of Fozivudine in context to a standard Zidovudine based antiretroviral therapy regimens after 24 weeks of treatment in ART naïve, non subtype B HIV-1 infected individuals from Tanzania and Ivory Coast
EDCTP Project Code:	MS.2010.10800.001
EDCTP Project Start Date:	6 October 2011
EDCTP Project End Date:	30 November 2014
Collaborating partners:	• Xavier Anglaret (INSERM, Unité 897, France) • Chales Nde Awasom (Bamenda Provincial Hospital, Cameroon) • Brigite Bazin (ANRS, France) • Ulrich Braun (Ludwig-Maximilians Universitat Munchen, Germany) • Gerd Burchard (Bernhard-Nocht-Institut for Tropical Medicine, Germany) • Christine Danel (Programme PACCI (Site ANRS Abidjan), Côte d'Ivoire) • Serge Paul Eholie (Service de maladies infectieuses et tropicales du centre hospitalier universitaire de Treichville (SMIT), Côte d'Ivoire) • Torsten Feldt (Bernhard-Nocht-Institut for Tropical Medicine, Germany) • Martin Fischer (Klinikum of the Ludwigs-Maximilians-University München, Germany) • Pierre-Marie Girard (University Hospital Saint-Antoine, France) • Sonja Henne (Ludwig-Maximilians Universitat Munchen, Germany) • Arne Kroidl (Klinikum der Universität München/NIMR-MMRP, Germany/Tanzania) • Jan van Lunzen (University Medical Center Hamburg-Eppendorf, Germany) • Leonard Maboko (NIMR-MMRP, Tanzania) • Betty Norman (Komfo Anokye Teaching Hospital, Ghana) • Papa Salif Sow (University of Dakar, Senegal) • Friedrich Adolf Herbert Otto Von Massow (Institute for Life Sciences and Environment (i-LSE) GmbH, Germany) • Alexander Zoufaly (Bernhard-Nocht-Institute for Tropical Medicine at the Bamenda Provincial Hospital, Cameroon) • Ralf Zuhse (Chiracon GmbH, Germany) • Juergen Reinhardt (United Nations Industrial Development Organisation, Austria) • Palu Dhanani (Universal Corporation Ltd.(UCL), Kenya) • Yan Ho Choo (Stada Vietnam, Vietnam)
Clinical Trial	**FATI-1**
Site Principal Investigator(s):	• Arne Kroidl (Tanzania) • Serge Eholie (Côte d'Ivoire)
Clinical Trial/Study Sponsor:	Clinic Study Centre, Klinikum of the University of Munich
Trial/Study title:	FATI-1: A prospective, multicenter Phase 2a trial to confirm a

	sustained virological suppression defined as HIV-RNA <50 copies/ml of 4 different doses of Fozivudine in context to a standard Zidovudine based antiretroviral therapy regimens after 24 weeks of treatment in ART naïve, non subtype B HIV-1 infected individuals from Tanzania and Ivory Coast
Goal:	The overarching goal of this evaluation is to help optimize the effectiveness of the antiretroviral treatment programs by identifying variables and characteristics that have the greatest impact on reducing treatment failure as defined by viral suppression.
Primary Objective(s):	To confirm a sustained virological suppression (HIV RNA <50 copies/ml) after 24 weeks of treatment between three different doses of Fozivudine (FZD) based antiretroviral 1st line treatment regimen in context to a standard Zidovudine (ZDV) based treatment regimen in non subtype B HIV-1 infected individuals from Africa.
Secondary Objective(s):	1. HIV-RNA log10 reduction of HIV-RNA at 2, 4 and 8 weeks of treatment between different arms 2. Virological response (HIV RNA <50 copies/ml) at 8 and 12 weeks of treatment between different arms 3. Virological response (HIV RNA <400 copies/ml) at 8, 12 and 24 weeks of treatment between different arms 4. Immunologic response: variation in CD4 lymphocytes between different arms 5. Drug toxicity, particularly anaemia, neutropenia and gastrointestinal adverse events 6. Resistance pattern for in patients with virological failure 7. Clinical trial capacity building of African study sites within the FATI network 8. Establishment of a Fozivudine Drug developing consortium (NET) including members of pharmaceutical manufacturers in Asia, Africa and Europe. 9. Development and piloting of a capacity development monitoring and evaluation framework
Clinical Trial/Study site(s):	The NIMR-Mbeya Medical Research Programme (MMRP) supporting the Mbeya Referral Hospital (MRH) (Tanzania) SMIT (Service de Maladies Infectieuses et Tropicales) in collaboration with the PACCI Program Abidjan (Côte d'Ivoire)
Collaborating site(s):	• INSERM, Unité 897 (France) • Ministry of Health through the Komfo Anokye Teaching Hospital (Ghana) • Bernhard-Nocht-Institut for Tropical Medicine (Germany) • Bamenda Provincial Hospital (Cameroon) • University Medical Center Hamburg-Eppendorf (Germany) • University of Dakar (Senegal) • University Hospital Saint-Antoine –and Institut de Médecine et d'Epidémiologie Appliquée (IMEA) (France) • French National Agency for Research on AIDS and Viral Hepatitis (ANRS) (France) • Chiracon GmbH (Germany) • Institute for Life Sciences and Environment (i-LSE) GmbH (Germany)
Study design:	Open-label, multicenter, prospective, randomised Phase IIa proof of concept and dose evaluating study. Arm A (N=30): FZD 600mg BD + 150mg 3TC BD + 600mg EFV OD Arm B (N=30): FZD 800mg OD + 300mg 3TC OD + 600mg EFV OD

	Arm C (N=30): FZD 1200mg OD + 300mg 3TC OD + 600mg EFV OD Arm D (N=30): AZT 300mg/3TC 150 mg BD + 600mg EFV OD *OD: Once daily *BD: Twice daily
Number of subjects:	A total of 120 ART naive HIV-1 infected individuals with the indication to start antiretroviral treatment according to WHO and country guidelines will be enrolled. Each of the two study sites will enrol 60 participants (15 participants per arm). A minimum of 30% female or male participants will be requested per site.
Product(s):	• Fozivudine (FZD) • Lamivudine (3TC) • Efavirenz (EFV) • Zidovudine (AZT)
Manufacturer/Developer:	FZD (Chiracon) and for the rest, they are available through national HIV programmes.
Cofunders:	• Federal Ministry of Education and Research (Germany) • National Agency for AIDS research/ANRS (France) • Chiracon GmbH (Germany) • Heidelberg Pharma AG (Germany) • University of München (Germany) • Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) (Germany)
Trial Registration number	PACTR201205000384379 NCT01714414
Status:	Ongoing
Results and Outcomes:	
Publications:	

1.5 TBTEA

EDCTP Project Coordinator:	Stefan Kaufmann (Max Planck Society, Germany)
EDCTP Call Title:	Call for the support of member states initiated projects within the scope of EDCTP activity areas
EDCTP Project Title:	Collaboration and integration of Tuberculosis Vaccine Trials in Europe and Africa
EDCTP Project Code:	MS.2010.1800.002
EDCTP Project Start Date:	2 September 2011
EDCTP Project End Date:	31 December2013
Collaborating partners:	• Abraham Aseffa (Armauer Hansen Research Institute, Ethiopia) • Mark Doherty (SSI, Denmark) • Leander Grode (Vakzine Projekt Management, Germany) • Willem Hanekom (University of Cape Town/Tuberculosis Vaccine Initiative, South Africa) • Andrew Kambuga (The Infectious Diseases Institute at Makerere University, Uganda) • Camille Locht (Institut Pasteur de Lille, Inserm, France) • Yukari Manabe (Makerere University, Uganda) • Markos Abebe (AHRI, Ethiopia) • Carlos Martin (University of Zaragoza, Spain) • Helen McShane (University of Oxford, UK) • Souleymane Mboup (CHU Le Dantec, Senegal) • Gilles Riveau (Espoir Pour La Santé, Senegal) • Søren Tetens Hoff (Statens Serum Institute, Denmark) • Jelle Thole (Tuberculosis Vaccine Initiative, The Netherlands) • Gerhard Walzl (Stellenbosch University, South Africa)
Study 1	Capacity Building/Networking
Site Principal Investigator(s):	Stefan Kaufmann (Germany)
Trial/Study title:	Collaboration and integration of Tuberculosis Vaccine Trials in Europe and Africa
Goal:	To build a sustainable platform where knowledge and know-how on clinical trials of ongoing and future clinical TB vaccine evaluations in Europe and Africa can be exchanged, where joint activities can be explored and coordinated, where clinical trials capacity will be improved, broadened, integrated, and where overlap and unnecessary duplication of work will be prevented by the creation of synergies.
Primary Objective(s):	1. Through sharing and exchanging of scientific, technological, clinical and infrastructural know-how and practical experiences between all involved European and African partners on the following clinical interactions, SSI-AHRI (H1/IC31), UOXF-SATVI and UOXF-LEDANTEC (MVA85A), and MPIIB-SUN (VPM1002). This will stimulated in a joint workshop (networking work package) and short term training of technical and laboratory staff with specific emphasis on novel and existing clinical assays 2. Through early and timely exchange of know-how and technology transfer between UNIZAR (MTBVAC) and INSERM (HBHA) with prospective African partners, to prepare and build (specific) capacity for future clinical trials on MTBVAC and HBHA. This will be stimulated through short term training and exchange visits of post doc fellows to the clinical sites 3. Through continuous north-north, north-south and south-south exchange and transfer of knowledge and

	technologies by Post docs, Students and PhDs on current, and novel or improved assays for clinical evaluation of immune responses towards all these vaccines, specifically regarding multi-parameter FACS based assays, HBHA-IGRA, and Mycobacterial Growth Inhibition Assays (MGIAs).
Collaborating site(s):	• Tuberculosis Vaccine Initiative (Netherlands) • University of Oxford (UK) • Statens Serum Institute (Denmark) • Universidad de Zaragoza (Spain) • Inserm U1019 (France) • AHRI (Ethiopia) • SATVI (South Africa) • Stellenbosch University (South Africa) • Infectious Diseases Institute (Uganda) • Espoir Pour La Santé (Senegal) • Hospitalier CHU Le Dantec (Senegal)
Cofunders:	• Federal Ministry of Education and Research (BMBF, Germany) • BMGF (USA) • EU FP7 programme (Belgium) • SSI (Denmark) • Wellcome Trust (UK) • AERAS (USA) • Innocash Programme (Spain) • Ministry of economy, finances and industry (France)
Status:	Ongoing
Results and Outcomes:	
Post-doc studies:	Title: Characterization of innate and memory phenotypes to TB and hormone modulations in apparently healthy children and adolescents across age Candidate: Liya Wassie Dubale (AHRI, Ethiopia)
	Title: Global transcriptome analyses of peripheral blood leukocytes from vaccinees to determine immunologic responses to vaccination Candidate: Pedro Moura Alves and Natalie Nieuwenhuizen (Max Planck Society of the Advancement of Science, Germany)
	Title: Evaluation of the robustness and sensitivity of mycobacterial growth inhibition assays to measure mycobacterial immunity, and use of this and other assays to evaluate MVA85A induced immunity in field trials Candidate: Iman Satti (University of Oxford, UK)
	Title: Evaluation of the robustness and sensitivity of mycobacterial growth inhibition assays to measure mycobacterial immunity, and use of this and other assays to evaluate MVA85A induced immunity in field trials Candidate: Benjamin Kagina (University of Oxford, UK)
	Title: Search for immunological correlates of protection for MTBVAC Candidate: Juan Ignacio Aguiló (University of Zaragoza, Spain)
Publications:	1. Maertzdorf J, Weiner III J, Kaufmann SHE. Enabling biomarkers for tuberculosis control. *Int. J. Tuberc. Lung Dis*. 2012; 16(9):1140–1148 2. Kaufmann SHE. Tuberculosis vaccine development: strength lies in tenacity. *Trends Immunol*. 2012, 33(7): 373-379

1.6 WANETAM plus

EDCTP Project Coordinator:	Assan Jaye (Medical Research Council (MRC) Laboratories, The Gambia)
EDCTP Call Title:	Call for the support of member states initiated projects within the scope of EDCTP activity areas
EDCTP Project Title:	Towards strengthening of the West African Node of Excellence for TB, AIDS and malaria: WANETAM plus
EDCTP Project Code:	MS.2010.18000.003
EDCTP Project Start Date:	27 October 2011
EDCTP Project End Date:	31 August 2014
Collaborating partners:	• Dissou Affolabi (Centre National Hospitalier de Pneumo-Phtisiologie, Benin) • Umberto D'Alessandro (Institute of Tropical Medicine, Belgium) • Bouke de Jong (Institute of Tropical Medicine, Belgium) • Bassirou Diarra (SEREFO, University of Bamako, Mali) • Luc Kestens (Institute of Tropical Medicine, Belgium) • Souleymane Mboup (University Cheikh Anta DIOP de Dakar (UCAD), Senegal) • Martin Manzi (MRC, The Gambia) • Alain Nahum (Centre de Recherche Entomologique de Cotonou (CREC), Benin) • Raffaella Ravinetto (Institute of Tropical Medicine, Belgium) • Halidou Tinto (Centre Muraz, Burkina Faso)
Study / Trial 1	**Capacity Building**
Site Principal Investigator(s):	Assan Jaye (The Gambia)
Trial/Study title:	Towards strengthening of the West African Node of Excellence for TB, AIDS and malaria: WANETAM plus
Goal:	To strengthen the existing WANETAM network with new network initiatives on HIV, TB, and malaria recently developed in the region
Primary Objective(s):	1. Capacity building and technology transfer to prepare West African institutions for the successful leadership and conduct of clinical trials 2. Creation of a network for regional scientific collaborations
Secondary Objective(s):	1. Establishment of links with the newly formed Belgium-supported TB network and the West African Platform for HIV Intervention Research 2. Involvement of new partners for TB and malaria 3. A practical GCP course co-developed by Dr. Halidou Tinto at the Clinical Research Unit Malaria in Nanoro (Burkina Faso) and Prof. Umberto d"Alessandro, with the support of the Clinical Trials Unit (Raffaella Ravinetto) at ITM 4. A course in biomedical engineering at the MRC Gambia 5. A course in laboratory management at the MRC Gambia 6. English language training at the MRC Gambia 7. Four Masters/ short course equivalents at the ITM in Antwerp 8. Hands-on TB training on second line drug resistance testing in Antwerp 9. Hands-on training on P. falciparum genotyping related to clinical trials in Antwerp in year 1, followed by transfer of this training to The Gambia 10. Two scholarships per year for WANETAM plus members to attend the annual Diplome Universitaire laboratory science

	course organized by Prof. Mboup in Dakar 11. A network meeting with workshop on “clinical research in Africa with specific attention to ethical issues 12. Strengthening of the WANETAM website
Cofunders:	• FOD Buitenlandse Zaken (Belgium) • Institut of Tropical Medicine (Belgium) • MRC (UK)
Status:	Ongoing
Results and Outcomes:	
MSc study:	Title: Master Public Health – Including 8-week Short Course Health Policy, Health Systems Management, Disease Control Candidate: TBD (Institut of Tropical Medicine Antwerp, Belgium) Supervisor: Marleen Boelaert, Umberto D’Alessandro and Marie Laga (Institut of Tropical Medicine)
Publications:	

1.7 QuinACT

EDCTP Project Coordinator:	Jean-Pierre Van Geertruyden (University of Antwerp, Belgium)
EDCTP Call Title:	Call for the support of member states initiated projects within the scope of EDCTP activity areas
EDCTP Project Title:	The impact of retreatment with an artemisinin-based combination on malaria incidence and its potential selection of resistant strains
EDCTP Project Code:	MS.2010.18000.004
EDCTP Project Start Date:	29 September 2011
EDCTP Project End Date:	28 February 2014
Collaborating partners:	• Robert Colebunders (Prince Leopold Institute of Tropical Medicine, Belgium) • Umberto D'Alessandro (Prince Leopold Institute of Tropical Medicine, Belgium) • Martin Grobusch (University of Amsterdam, The Netherlands) • Pascal Lutumba (University of Kinshasa, Democratic Republic of Congo) • Raffaella Ravinetto (Institute of Tropical Medicine, Belgium) • Hypolite Muhindo (University of Kinshasa, Democratic Republic of Congo) • Carolyn Nabasumba (Mbarara University of Science and Technology, Uganda) • Halidou Tinto (Centre Muraz, Burkina Faso) • Andrew Kambugu (Infectious Diseases Institute, University Makarere, Uganda) • Ambrose Talisuna (Regional Scientific Director, East Africa • World Wide Antimalarial Resistance Network (WWARN), Uganda)
Clinical Trial	
Site Principal Investigator(s):	• Carolyne Nabasumba (Uganda) • Hypolyte Muhindo (RD Congo)
Clinical Trial/Study Sponsor:	University of Antwerp (Belgium)
Trial/Study title:	The impact of retreatment with an artemisinin-based combination on malaria incidence and its potential selection of resistant strains
Goal:	To identify if first line ACT can be safely and efficaciously used to retreat children with recurrent malaria occurring beyond 14 days after initial treatment and consequently preserve quinine for severe malaria treatment.
Primary Objective(s):	1. To determine the safety and efficacy of 2 ACTs (ASAQ and AL) vs quinine when administered to children under five with recurrent *P. falciparum* infection and to collect explanatory variables for treatment failure (PCR corrected) and for recurrent parasitaemia 2. To develop disease-endemic country (DEC) research capacity through training and professional development of scientists, building of infrastructure and transfer of technology 3. To coordinate research efforts on treatment and prevention tools of malaria in children and, by doing so, finalise a common research agenda and promote the rational use of available resources.
Clinical Trial/Study site(s):	• Lisungi Health Center (Democratic Republic of Congo) • Makerere University (Uganda)

Collaborating site(s):	• Institut de recherche en science de la santé (IRSS/DRO) / Centre Muraz (Burkina Faso) • Prince Leopold Institute of Tropical Medicine (Belgium) • Stichting AMC CPCD Foundation (Uganda) • Academic Medical Centre at the University of Amsterdam (Netherlands)
Study design:	Two-centre, non inferiority, phase III, randomised, open label, 3-arm trial
Number of subjects:	3600; 1800 children (between 12 and 59 months inclusive) per site
Product(s):	• Quinine • Artemether-lumefantrine (AL) • Amodiaquine artesunate (ASAQ)
Manufacturer/Developer:	All products used in this trial are available through national programmes
Cofunders:	• University of Amsterdam (Netherlands) • Research Foundation Flanders- FWO (Belgium)
Trial Registration number	NCT01374581
Status:	Ongoing
Results and Outcomes:	
PhD studies:	Title: The impact of retreatment with an artemisinin-based combination on malaria incidence and its potential selection of resistant strains? Candidate: Hypolite Muhindo (University of Kinshasa, Democratic Republic of Congo) Dates: September 2011-June 2013
	Title: Antimalarial treatment in the Greater Mbarara district, Uganda: efficacy, use and access Candidate: Carolyn Nabasumba (Epicentre Mbarara Research Base, Mbarara University, Uganda)
Publications:	

1.8 Kreidenweiss

EDCTP Project Coordinator:	Dr Andrea Kreidenweiss (University of Tübingen, Germany)
EDCTP Call Title:	Support for Member States Initiated (MSI) Projects within the scope of EDCTP activity areas
EDCTP Project Title:	Enhancing research capacities through the joint development of a multiplex flow cytometric bead assay for polyparasite detection in pregnant African women
EDCTP Project Code:	MS.2011.10800.001
EDCTP Project Start Date:	1 October 2012
EDCTP Project End Date:	31 May 2014
Collaborating partners:	• Adrian Luty (Institut de Recherche pour le Développement (IRD), France) • Marguerite Massinga Loembé (Medical Research Unit (MRU), Gabon)
Goal:	The overall aim of this German/French/Gabonese MSI project is to develop a novel diagnostic tool that allows for the simultaneous identification of multiple parasitic infections present in a single individual using a single smallvolume sample of plasma including the particular emphasis of detecting malaria in pregnant African women.
Primary Objective(s):	To develop an assay for detection of multiple parasitic infections during pregnancy including potentially cryptic placental Plasmodium falciparum. This MSIP is based on the joint expertise of the German and the French research projects where the Germans bring in the microbead platform for simultaneous parasite detection and the French their competence in pregnancy-associated malaria. Therefore, VAR2CSA will be evaluated for its potential as a biomarker for P. falciparum infection detected in a patient blood sample.
Clinical Trial/Study site(s):	Medical Research Unit (Gabon)
Collaborating site(s):	• University of Tübingen (Germany) • Institut de Recherche pour le Développement (France)
Status:	Ongoing
Results and Outcomes:	Pending
PhD studies:	Title: Implementation of a multiplex flow cytometric bead assay for polyparasite detection in African pregnant women Candidate: Anthony Ajua (Medical Reseach Unit, Gabon) Dates: 1 March 2013 – TBD
Postdoc studies:	Peter Soboslay (Medical Reseach Unit, Gabon)
Publications:	Pending

1.9 XACT (Dheda)

EDCTP Project Coordinator:	Professor Keertan Dheda (University of Cape Town, South Africa)
EDCTP Call Title:	Support for Member States Initiated (MSI) Projects within the scope of EDCTP activity areas
EDCTP Project Title:	The utility of intensified case finding combined with a package of novel TB diagnostics using a mobile clinic in Africa- a randomized controlled trial (XACT)
EDCTP Project Code:	MS.2011.10800.003
EDCTP Project Start Date:	1 November 2012
EDCTP Project End Date:	31 December 2014
Collaborating partners:	• Lynn Zijenah (University of Zimbabwe Collesge of Health Sciences, Zimbabwe) • Leonardo Sechi (University of Sassari, Italy) • Bram van Ginneken (Radboud University, The Netherlands)
Clinical Trial	The XACT study
Site Principal Investigator(s):	• Keertan Dheda (South Africa) • Lynn Zijenah (Zimbabwe)
Clinical Trial/Study Sponsor:	University of Cape Town
Trial/Study title:	The utility of intensified case finding combined with a package of novel TB diagnostics using a mobile clinic in Africa- a randomized controlled trial (XACT)
Goal:	The use of point-of-care diagnostic tools (system screening, HIV and urine LAM strip testing, and GeneXpert MTB/RIF) will be compared to standard methods (system screening, lab-based sputum smear microscopy and culture) for intensive case to determine which arm will significantly increase the proportion of TB cases initiating and completing TB treatment. Thus, we seek to determine what package of novel point-of-care diagnostics technologies can add to active case finding.
Primary Objective(s):	The proportion of culture-positive TB cases initiating TB treatment in each study arm
Clinical Trial/Study site(s):	• Langa and Gugulethu communities (South Africa) • Mabvuku district, Zimbabwe
Collaborating site(s):	
Study design:	Randomised controlled trial
Number of subjects:	800 (400 per site)
Product(s):	GeneXpert
Manufacturer/Developer:	Cepheid (USA)
Cofunders:	• Radboud University (Netherlands) • Istituto Superiore di Sanità Dipartimento del Farmaco (Italy) • University of Cape Town (South Africa) • University of Zimbabwe (Zimbabwe) • Alere Diagnostics (South Africa) • DST (South Africa)
Trial Registration number	NCT01990274
Status:	Ongoing
Results and Outcomes:	Pending
PhD studies:	
Publications:	