



ASAAP NEWSLETTER

The Official Newsletter of **ASAAP Project** | No. 03 | **June 2024**

... stronger together

Project Updates

ASAAP Annual Meeting

During the peak of our recruitment efforts and the implementation of the Main study, an annual meeting was held in Cotonou, Benin from 06-07 June 2023. The purpose of the meeting was to reinforce our collaboration through the exchange of profound ideas, address the challenges encountered, and develop practical and realistic solutions to ensure the timely completion of the project. The meeting was attended by team members of the various WPs, Leads and Co-leads, Study Coordinators from all partner institutions. In attendance was also Pharmalys, the Contract Research Organization (CRO) for the ASAAP trial. Over the course of these two days, the meeting featured presentations and interactive sessions aimed at addressing various challenges related to the study. These discussions encompassed the streamlining of data collection and handling

of queries, as well as the harmonization of safety reports. Furthermore, the gathering provided a valuable opportunity to engage with investigators and study coordinators, enabling discussions on recruitment rates and strategies to enhance participant enrollment across the study sites. ASAAP Student fellows have also the opportunity to present the progress made in their MSc/PhD project. ↻

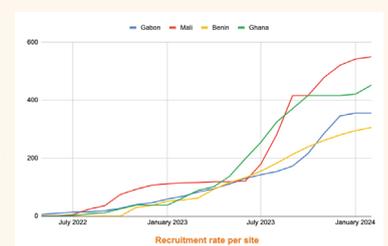


Extra Funding secured: ASAAP Plus

ASAAP Plus is a 24-month project awarded by the HORIZON-JU-GH-EDCTP3-2023-01-02 program to successfully finalize EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic. This grant supports the remaining activities under ASAAP RIA2017MC-2022-EDCTP2 until December 2025. Following the submission of a proposal in July 2023, it was competitively selected and the grant has been fully executed in January 2024. ↻

Target Recruitment Achieved

The enrollment target of 416 per study site has been successfully met in Mali and Ghana in September and October 2023 respectively. This represented a significant milestone in the project, Nevertheless, in pursuit of the main study's objective to reach the total recruitment goal of 1664 participants, the consortium collectively decided to implement **a competitive recruitment strategy**. This approach enabled us to continue enrolling additional participants until the target sample size recruitment was met in February 2024. Follow up period was concluded end of April 2024. ↻



Project Update

Community engagement within the ASAAP project

Capacity Building

Editorial Corner

Community engagement within the ASAAP project: Read about the strategies employed by the PIs and the study Coordinators.

@Gabon (CERMEL)

In the framework of the ASAAP project the Gabon team initiated community engagement activities with the aim to contribute to the control of malaria while conducting the clinical trial. The objectives include engaging the communities in Strengthening malaria diagnostic capacity where needed, Improved malaria case management and Sustained research capacity.

To reach the objectives, community meetings held with village chiefs and leaders identified the need for enhanced malaria diagnosis and management.



A mobile laboratory, equipped for microscopy, haematology, and biochemistry, reached remote rural areas especially in areas where the public transport could not reach.



Additionally, satellite sites were established in Sindara in the Ngounié province, in Mighoma/Tchibanga in the Nyanga province and in Four-place in the Estuaire province. The establishment of satellite sites goes with the implementation of a health and

demographic surveillance system locally called SUDESA (suivi démographique et sanitaire).

CERMEL, the National Malaria Control Program (NMCP), and the Centre Hospitalier Régional de Tchibanga signed a convention for CERMEL's supervision of a sentinel site for malaria. The NMCP stays informed of study progress, and the community is updated annually during World Malaria Day events. ↻



@Mali (MRTC)

The ASAAP study centered around the Faladie, a rural village situated at 75 km from Bamako. Faladie serves as the focal point for the MRTC's extensive engagement spanning over two decades in the municipality of N'djiba, comprising 23 villages, resulting in a positive relationship with the local population and community leaders.



Before initiating any research study, a meticulous process is followed. Initial ethical approval is sought from the USTTB Ethics Committee, after which appointments with community leaders are facilitated through local contacts

or study guides. In these meetings, the entire study team, when feasible, seeks the community's consent. The principal investigator communicates the study's protocol in the local language, emphasizing its significance, potential benefits, and associated risks. Community leaders provide valuable input, and the team addresses any queries raised. After securing consent, the team engages with administrative and health authorities, particularly at the Catholic Health Center in Faladie, where participant recruitment and hospitalization occur. Effective communication with church leaders ensures a thorough understanding of the study's protocol.



Prior to each participant's inclusion, explicit consent or assent is obtained. The team, operating from the Catholic Health Center, also extends care for other diseases, even if the patient is not part of the study. To enhance community engagement, local guides play a crucial role, reminding participants 24 hours before follow-up visits and actively seeking participants who may face challenges attending. This comprehensive approach underscores the commitment to ethical practices, community involvement, and effective communication in the ASAAP study in Faladie. ↻

@Benin (IRCB)

The ASAAP project in Benin prioritized extensive community engagement throughout the clinical trial implementation process, involving various interview formats, stakeholder interactions, and community-level initiatives. Interviews, information sessions, and focus groups were conducted, engaging approximately 300 individuals, including health officials, ethics committees, community leaders, and women's associations.

In Dodji-Bata, six facilitators, including literacy teachers and pastors, played a pivotal role in translating consent forms into the local language and working closely with community relays and village chiefs to ensure local comprehension. Awareness sessions, featuring audio versions of consent forms, reached around 60 people per village, totaling 2880 individuals in Dodji-Bata. Subsequently, awareness-raising initiatives commenced in the SEKOU district in July 2023, supervised

by ASAAP team members and health center staff.



In addition to awareness sessions, two weekly mobile clinic sessions in SEKOU included slide readings and free malaria treatment for children aged 6 months to 10 years. Town criers were utilized to inform the community about the free malaria treatment. The community engagement efforts significantly increased prescreening during outreach sessions, contributing to enhanced recruitment. 🕒

@Ghana (KCCR)

The ASAAP study in Ghana is conducted at the St Francis Xavier Hospital located in the Assin Foso municipality.

Since the inception of the ASAAP study, there has been several community engagement activities conducted to encourage positive health seeking behavior in the study area. These activities begin at the district level with the health directorates who provide a list of contacts for their sub-districts and inform them of our activities in their locality.



Health volunteers and in-charges of the health clinics from each community are engaged throughout the study to ensure better operationalization of the study conduct. Also, At the beginning of the

study team provided general information on the study during a radio broadcast, allowing to answer direct questions from the auditors and discuss the very prevalent issue of self-medication within the community.

The recruitment strategy in Ghana is based on community screening. The screening days are announced to the rest of the people using the community information centers and the health volunteers assist in mobilizing the people and setting up for the screening. Health education is an integral part of the community screening and engagements, addressing common misconceptions about malaria and malaria prevention.



Other form of engagement has been made through gathering at the middle of the recruitment to provide general feedback and seek of ways to improve our interaction with them. The community activities have given us rich perspectives into the social determinants of the success of the study and clinical research in the area and has helped us to provide more holistic care to our participants and indeed to the communities who have stood with us in this endeavor. 🕒

Capacity Building

Genetic Training Workshop

Dr. Jérôme Clain (IRD) and Prof. Achille Massougboji (IRCB) leading the genetic analysis workpackage of the ASAAP project organized a 2 weeks training at the Centre d'Étude et de Recherche sur les Pathologies Associées à la Grossesse et à l'Enfance (CERPAGE - Calavi) and Institut de Recherche Clinique du Bénin (IRCB) in Benin from the 09 January, 2023 to 14 January, 2023. In order to harmonize the molecular laboratory activities and to build capacities, 10 of the laboratory technicians and engineers from the 4 study sites in Gabon, Mali, Ghana and Benin attended this intensive training course on PCR correction using markers of clonality such as msp1, msp2 and microsatellites, Sanger sequencing, and quantitative PCR for detection of drug resistance markers. The face to face training was preceded by

online meetings to familiarize with all standard procedures. The training equipped the participants with a better understanding of the ASAAP project, the importance of genotyping activities in the project and the autonomy of the participants in carrying out the experiments and analyzing the genetic data. ↻



Data Analysis Workshop

The Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR) in collaboration with the Bernhard Nocht Institute for Tropical Medicine (BNITM) hosted intensive 10-days workshop on epidemiological methods, clinical studies, and hands on data analysis from 09 to 18 October 2022. This training course brought together an international and multidisciplinary group of 14 junior researchers from the African partnering countries involved in the ASAAP studies (Benin (IRCB), Burkina Faso (INStech), Mali (MRTC), Gabon (CERMEL) and Ghana (KCCR) to enhance their understanding of epidemiology and clinical study design. The training segment "Basic Epidemiology with Stata (BASES)" covered fundamentals in epidemiological study designs, data management, and analysis techniques using Stata. The workshop included lectures and hands-on exercises led by faculty from Ghana and Germany and provided

participants with the opportunity to apply their knowledge to research data. The second segment on "Clinical Trials: Design and Analyses", led by Dr. Eva Lorenz (WP5 Team), Solomon Wafula (WP5 Team) and Ralf Krümekamp (BNITM). provided the opportunity to focus on clinical trial data analysis where participants presented their doctoral and master's projects. This workshop provided a platform for valuable feedback and assistance with analysis strategies. ↻



Student Highlight: Cheick Papa Oumar Sangare



Cheick Papa Oumar Sangare is a clinical investigator at the ASAAP study site in Faladje, Mali. With the help of EDCTP funding, he enrolled for his PhD in Nutrition at the Ecole Doctorale des Sciences et Technologies du Mali (EDSTM) at the Université des Sciences, des Techniques et des Technologies de Bamako (USTTB). Currently in his third year, his research focuses on the dietary and nutritional profiles of children from 6 months to 10 years of age under anti-malarial treatment with the tri-therapy Artemether-Lumefantrine + Atovaquone-Proguanil in Mali.

The first year was involved in validating several modules at the Ecole Doctorale des Sciences et Technologies, such as Research Methodology and Scientific Writing. These validations enabled him to

acquire a deeper understanding of scientific research. Data collection began in the second year. To date, 416 children have been included in the study. The dietary and nutritional profiles of these children will be determined by measuring various z-scores, brachial perimeter and body composition. These results will enable to determine whether there is a relationship between nutritional status and parasite clearance after treatment, and more precisely whether there is a link between nutritional status and the efficacy of Artemether-Lumefantrine + Atovaquone-Proguanil triple therapy in Mali. Thanks to EDCTP funding, ASAAP has given Dr Cheick Papa Oumar Sangare the opportunity to carry out this research as part of its capacity-building in the field of Nutrition-Malaria. ↻

Anopheles stephensi in Africa, what are the Implications for Malaria Control?

A Malaria Threat

Africa, already grappling with a high burden of malaria cases and related deaths, faces an increased threat due to *An. stephensi*'s presence. The World Health Organization has recognized this mosquito as a significant threat and called for global monitoring of its detection, establishment, and spread. ☹️

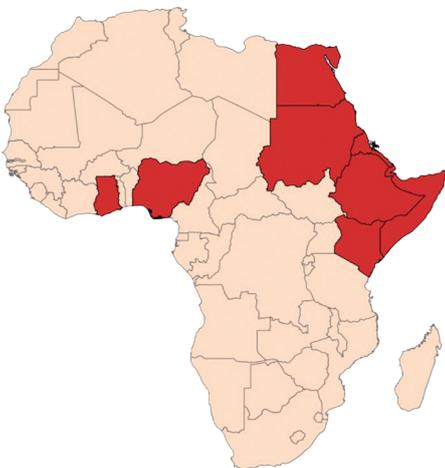


Fig. 1. Countries in red have reported the presence of *An. stephensi* on at least one occasion.

- Egypt
- Djibouti
- Ethiopia
- Sudan
- Nigeria
- Eritrea
- Ghana
- Kenya
- Somalia
- Tanzania

Ref: Pecor, D.B., Potter, A.M. & Linton, Y.M. Implications of Climate Change and *Anopheles stephensi* Liston in Africa: Knowledge Gaps and Lessons from History. *Curr Trop Med Rep* 10, 320–330 (2023). <https://doi.org/10.1007/s40475-023-00296-7>

The introduction and Spread of *An. stephensi* in Africa

The introduction and spread of *Anopheles stephensi*, an invasive Asian malaria mosquito, in Africa present serious implications for malaria control efforts on the continent. This mosquito first appeared in Djibouti in 2012, likely through cargo transport, and has since established itself and expanded its distribution across multiple African countries. Factors such as urbanization, climate change, and insufficient vector surveillance have facilitated its rapid expansion. In January 2023, Ghana reported for the first time the presence of *An. stephensi* in the country. This is the second country in west Africa, After Nigeria to report the presence of the deadly mosquito. ☹️

Implications for Malaria Control

An. stephensi is known for its high vector capacity, capable of transmitting both *Plasmodium falciparum* and *P. vivax* parasites to humans. It has been associated with unusual malaria outbreaks in urban areas. Unlike some other malaria vectors that breed in natural puddles, *An. stephensi* utilizes human-built water storage facilities, allowing it to sustain its population throughout the year. This mosquito's preference for urban and peri-urban environments highlights the need for proactive policies and plans to control and eliminate its population in cities. A study estimated 126 million people at risk for malaria if *An. stephensi* continues its invasion across the continent. *An. stephensi*'s resistance to multiple insecticides and its distinct feeding and resting behaviors challenge traditional vector control methods. It can also survive extreme temperatures during the dry season, altering malaria transmission dynamics. Consequently, new tools and strategies are required to control its population, especially in areas where it is not native. ☹️

Prevention is Always Better Than Cure

Preventive measures should include surveillance in seaports to detect and model marine cargo traffic, identifying high-risk countries for invasion. Early detection should lead to strategies to locate and modify potential larval sites. Surveillance efforts should encompass *Aedes* mosquitoes due to overlapping larval sites and the monitoring of arboviruses. African countries facing the spread of *An. stephensi* should adopt WHO's initiative to combat its proliferation. This initiative includes knowledge sharing, combined vector control methods, research on mosquito behaviors, community awareness, and education, as well as monitoring drug and insecticide *An. gambiae*. However, this goal requires addressing the knowledge gap related to resistance. History shows that the elimination of invasive mosquito species is possible, as seen in Brazil with *An. stephensi*'s detection, establishment, and spread.

In conclusion, the introduction of *An. stephensi* in Africa demands a comprehensive and collaborative approach to safeguard public health and control the spread of malaria. ☹️

To Read - WHO: Partners convening: a regional response to the invasion of *Anopheles stephensi* in Africa: meeting report, 8–10 March 2023



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