



NEWSLETTER



Investigator Meeting & Project Board Meeting

15th and 16th of March 2022- Lambaréné, Gabon

As part of the WANECAM 2 programme activities, the Investigator meeting and programme management was held on March 15th and 16th, 2021 at the Lambaréné Medical Research Center in Gabon (CERMEL). Welcomed by Doctor Rella Manego, the principal investigator of the study for the Gabon site and Prof. Ghyslain Mombongoma, the opening ceremony was held in the presence of Dr Julien, Regional Director and the Prof. Ayola Akim Adegnika, Director of CERMEL.

Activities:

Investigators from the study sites in Burkina Faso, Gabon, Mali, and Niger shared updates on their progress. Moreover, work package leaders presented what has been achieved so far and their plan to move forward in terms of capacity building, clinical research aspects, communication needs and networking.

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The presentations provided a clear overview of the work done so far by the consortium as well as the activities still to be organized by all involved parties. For the KALUMI trials on KAF156/LUM-SDF for the treatment of acute uncomplicated malaria in infants, the planned run-in cohort where data was gathered on efficacy, safety and pharmacokinetics of the drug taken with or without a meal has been completed. Before hopefully moving on to the phase 3 trials, a second run-in cohort receiving different dosing of KAF156/LUM-SDF and a cohort of children from 6 months to <12 years will be studied.

For KALUMA, the phase 3 trials investigate the efficacy, safety and tolerability of ganaplacide-lumefantrine compared with Coartem® in adults and children > 5kg of body weight and the safety of ganaplacide lumefantrine repeated dosing. The trial is planned to start in 2023.

The meeting was concluded by a closing ceremony to thank CERMEC logistic Team and participants. The participants went on a guided visit to the Lambaréné study site as well as that of the museum dedicated to Dr. Albert Schweitzer.



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Description of geography and other practical aspects of the study sites

Mali

Bougoula-Hameau

Bougoula-Hameau is a suburb consisting of 6,900 inhabitants, located five kilometers from the city of Sikasso. It is located in the Sudano-Guinean savannah zone dominated by large trees and tall grass. It is a rainforest zone with a rainy season lasting up to six months at least. Malaria transmission is seasonal, with peak transmission occurring from May to November. The predominant ethnic groups are Senoufo, Samogo, Mossi, Fulani and Bambara. The area is rural, with agriculture being the main economic activity. The Sikasso region receives more rain than any other region in Mali and is known for its fruits and vegetables.

Level of capacity building and status of clinical trial

Bougoula-hameau has a community health center (CSCoM) that hosts the WANECAM 2 research site. The research center is made up of two blocks, a first block located in the CSCoM compound and a second block that was built through cooperation with the French Development Agency (AFD). WANECAM 2 has allowed the development of the research center, water supply and installation of electricity in the new building (AFD block).

To date, the total number of patients screened is 44. Among them, 21 patients have been enrolled at the Bougoula site where 2 clinicians, 3 biologists and a local support staff are working. The challenges encountered concern the protocol age and weight range required as per inclusion criteria. This, together with the dry season, means that teams had difficulty finding cases to include at the moment.

Kollé

Kollé located about 57 km southwest of Bamako in the Sudano-Guinean zone of Mali. The Djoliba site is in the Kollé area (site 1102) and is part of the latter's catchment area. The research center is the only center there that provides primary health care and is involved in scientific research. These activities are carried out by the MRTC-Parasito team.

Level of capacity building and status of clinical trial

WANECAM 2: Kollé and Djoliba were renovated in 2020 to meet the research requirements of the area. These activities included renovation and expansion of the center, the installation of solar panels in Djoliba and a generator in Kollé.

The team consists of 3 clinicians, 3 biologists and local support staff. A total of 22 patients were screened, of which 10 successfully completed the process, 11 failed the screening and 1 was lost of follow up.

The main challenge encountered at the Kollé site is equipment back-up. The site is located about 60kms from Bamako and the team must transport samples to Bamako for testing.

To increase patient recruitment, the inclusion zone was extended to 6 km from the site.

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Description of geography and other practical aspects of the study sites

Sotuba

Sotuba is a peri-urban neighborhood of Bamako. The Sotuba research site (Site 1 101) is an independent site that hosts only Malaria Research and Training Center (MRTC) activities. This site also houses a certified molecular biology laboratory.

Level of capacity building and status of clinical trial

For capacity building, 2 new laboratory automated machines, 1 new car and 2 new high resolution microscopes were purchased. Enrollment began on July 26, 2021 and 17 patients have been screened with 8 failures. The team consists of 3 clinicians, 3 biologists and support staff.

Distribution of enrollments by site in Mali

In total, the 3 sites in Mali (Bougoula-Hameau, Sotuba and Kollé) have strongly contributed to the PK Run-in and Cohort 1 part of the KALUMI study with a total enrollment of 36 patients distributed as follows (see table below)

Site name	Total number screened	Total enrolled	Total completed follow-up	Discontinued
Bougoula-Hameau (1100)	44	21	19	2 (1 discontinued & 1 loss of follow-up)
Sotuba (1101)	17	9	7	2
Kollé (1102)	22	11	10	1

All Mali study sites are currently open for patient enrollment for cohort 2 of KALUMI.

Acquired equipment



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Description of geography and other practical aspects of the study sites

Burkina Faso

Gras



Groupe de Recherche Action Santé (GRAS) is a research institute under private law of international reference, based in Ouagadougou, Burkina Faso. With a wealth of qualitative research personnel, GRAS's main motivation is to boost the contribution of the private sector in health research alongside the public sector. This is why it presents itself as a framework for grouping, expressing and exchanging skills to promote excellence for the benefit of human health.

Within the framework of the implementation of the activities of the WANECAM2 program GRAS has, through the principal investigator, Dr. Sodiomon Bienvenu SIRIMA developed the following actions:

- Establishment of a project team to conduct the project
- Capacity building of the clinical biology laboratory with the acquisition of equipment
- Preparation of the sites for the conduct of the clinical trial
- Submission and obtaining approval from the ethics committee and the Ministry of Health for the conduct of the clinical trial

Status of clinical trials

After obtaining the necessary approvals and authorizations, the initiation visit for the GRAS site (site 1000), was conducted on October 14, 2021.

The site was not able to participate in the first two rounds of enrollment of the first patients of the entry cohort which closed on November 5, 2021. However, as of the opening of the 3rd round of enrollment of the entry cohort, GRAS has just enrolled the first patient on its site on February 1, 2022, corresponding to the first patient of this round at the WANECAM 2 network level. Screening is still ongoing for the enrollment of new patients. In parallel, in order to prepare the next enrollments for cohort 1 and cohort 2, GRAS has introduced an amendment for the extension of the study to other sites located in other areas with different epidemiology favorable to the recruitment of large numbers of study participants. Finally, training in financial management of the project was provided to the Niger team by GRAS.

Received equipment



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Description of geography and other practical aspects of the study sites

Burkina Faso

INSTech

The Institute of Science and Technology (INSTech) is an institution for higher education. The main objective of the institute is the development of higher education, scientific research, employability, service provision, and the training of executives and technicians capable of participating in the socio-economic development of Burkina Faso. INSTech is involved in the WANEAM 2 program through its Director, Professor Jean Bosco OUEDRAOGO.

Level of capacity building and status of clinical trial

Revisions of standard operating procedures, formalization of staff contract, training and refreshment courses on good clinical practice and good laboratory practice, training on laboratory procedures (microscopy, haematology, biochemistry) and ECG have been conducted. Contracts with CSL for malaria microscopy competency testing have been arranged. Other contracts were made for CAP certification in haematology and biochemistry and for maintenance with ARCOA. All sites have been upgraded and equipped laboratories are now in place.



Permission to include study participants has been granted. Numerous documents are approved (ethics, import license, clinical research regulatory committee) and a collaboration agreement has been signed with the Regional Health Department.

The site has recruited a master student and a doctoral student. The master student has been trained in field and laboratory procedures.

The site's initiation visit, ECG training, and ethics accreditation renewal are underway.

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Description of geography and other practical aspects of the study sites

Gabon

CERMEL

The Centre de Recherches Médicales de Lambaréné (CERMEL) is a well-established institute for research in tropical medicine in the Central African sub-region. CERMEL is involved in the WANECAM 2 project as a patient recruitment site and also as a member of the Project Board and co-lead of Workpackage 5.

Within the framework of the WANECAM 2 program, capacity building has been focused on three aspects:

- General capacity building training
- Training in Good Clinical Practices (GCP): a training in GCP was conducted before the start-up
- Training of microscopists conducted by IQLS to upgrade their level on the realization of thick drop slides and blood smears, as well as their reading.
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Level of capacity building and acquiring needed equipment

The WANECAM2 program has enabled the upgrading of the infrastructure of CERMEL's sentinel sites. This upgrade consisted in the extension of buildings and water and electricity supply systems. With the seasonality observed at the beginning of 2022 with CERMEL as the only site able to recruit, it is planned to further strengthen the sentinel sites in order to widen their recruitment scope and increase the chances of recruitment.

WANECAM 2 has contributed with other budgets to the acquisition and equipment of a mobile laboratory.



The CERMEL site is in the process of acquiring an automated thyroid function analyser (TSH and T4), a minividas, and also an automated reticulocyte counting machine, the Pentra XLR.

Status of clinical trials

The first patient in Gabon was included on June 23, 2021, in the Run-In cohort 1. A total of 11 patients have been randomized in Gabon in this cohort. Recruitment in the Run-In cohort 2 started on February 04 and as of March 10, 9 patients have been randomized and their follow-up is ongoing.



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Description of geography and other practical aspects of the study sites

Niger

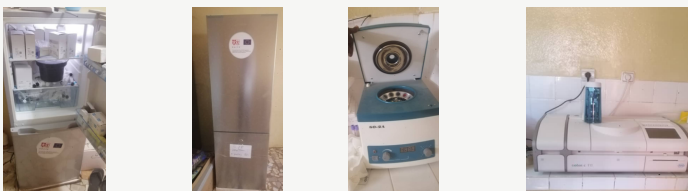
The study site consists of a building integrated within the health center of Koira Tégui located in Health District 2 of the Urban Community of Niamey with a staff of 32 employees and a total estimated population of 74.558 inhabitants. The building is composed of four rooms including a laboratory, an office for the doctors and two hospitalization rooms.

Level of capacity building and status of clinical trial

At the beginning of the WANECAM 2 study, work began with two rooms. The first was equipped with a consultation office, two desks, a consultation bed and two filing cabinets. The second room contained four hospital beds. The WANECAM 2 project contributed to improvement of the facility that involved the renovation of the building into laboratories, investigators' offices, hospitalization rooms for patients and toilets



New equipment was received including laboratory equipment and office equipment and the building has been equipped with a solar back-up system in case of power outage.



Site personnel have been trained on the overall study vision, GCP/GCLP and Niger standards study protocol, biology, and biochemistry. A PhD student involved in the project is enrolled at the University of Bamako and an involved MSc candidate will begin classes in 2022.

At the site, a study on the in vivo sensitivity of *P. falciparum* and other species to artesunate pyronaridine and artemether lumefantrine has already been conducted. In 12 months, the team enrolled 240 patients with uncomplicated malaria and followed them up for 42 days. A second study on biological and biochemical standards is underway. This study is planned to be conducted over two periods (rainy season and hot season), each requiring 520 healthy participants. The parameters studied are blood count, azotemia, creatinine, AST and ALT, total bilirubin, direct bilirubin and indirect bilirubin. Five hundred and twenty participants have already been enrolled for the rainy season. Enrollment is planned during the dry season.

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Description of geography and other practical aspects of the study sites

France

LYON 1

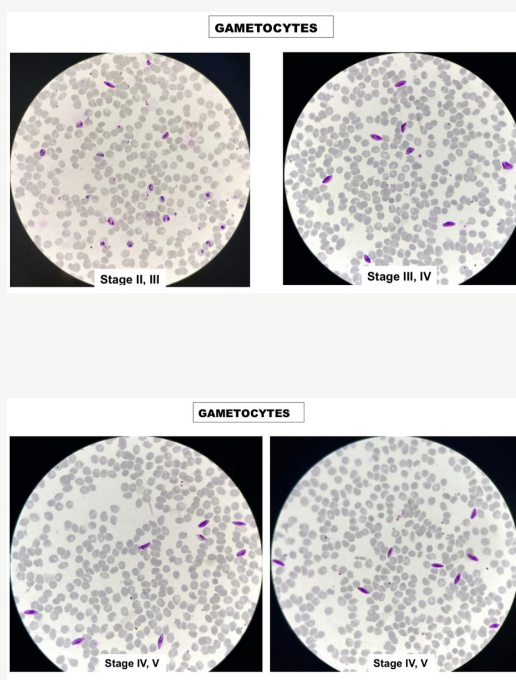
The Malaria Research Unit of the Faculty of Medicine at the University of Lyon 1 in France is dedicated to the analysis of the molecular mechanisms involved in the growth of *Plasmodium falciparum* and *Plasmodium vivax* in vitro, pathogenesis in mice and humans and resistance to antimalarial drugs. In the framework of the WANECAM 2 project, the URM team is working on the in vitro and ex vivo evaluation of the effect of KAF156 / LUM-SDF on *P. falciparum* gametocytes.

Progress of in vitro and ex vivo studies on the effect of KAF156 / LUM-SDF on gametocytes

- In vitro production of gametocytes for chemo-sensitivity testing.
- The production of gametocytes has been successfully completed.
- The protocol is currently being optimized.
- Gametocytes can be cryopreserved for use in standardized tests and other tests requiring reference parasites.
- Cryopreservation of gametocytes was achieved with a yield of 36% after thawing. This needs to be optimized.
- Clinical samples must be transported from the field to the laboratory before performing ex vivo tests in particular. Thus, they determined the cryopreservation protocol that can preserve samples during transport.

P.falciparum parasites can be cryopreserved in liquid nitrogen with 28% glycerol for an extended period of time. In addition, they can be cryopreserved at -20°C with the same cryo-protection for up to one month. This is useful for remote areas where liquid nitrogen is not yet available.

In the future, we plan to adapt these protocols to apply for clinical samples and perform chemo-sensitivity testing.



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Word of thanks

We would like to thank all contributors for sharing their updates and informing us on the work done at their respective WANECAM 2 study sites. Thank you to all stakeholders involved, especially EDCTP, Novartis and MMV.

We hope to share more news about the project with you soon.

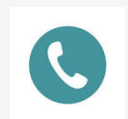
Our strategic partners



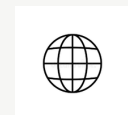
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