GROUPE DE RECHERCHE

GRAS

ACTION EN SANTE



2020 ANNUAL REPORT

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ABBREVIATIONS

ABMAQ : Association Burkinabè pour le Management de la Qualité

AL : Artemether-Lumefantrine

CIDRZ : Centre for Infectious Disease Research in Zambia

DHQ-AQ : Dihydroartemisinin-Piperaquine

HS : Health Service

EDCTP : European & Developing Countries Clinical Trials Partnership

EPI : Enlarged Program of Immunization

EVI : European Vaccine Initiative

GRAS : Groupe de Recherche Action en Santé

PI : Principal Investigator

IRSS : Institut de Recherche en Science de la Santé

IVI : International Vaccine Institute

MESRSI : Ministère de l'Enseignement Supérieur, de la Recherche Scientifique et de l'Innovation

MFT : Traitements en première intention multiples

MFT : Multiple First Lines Therapies

MMV : Medicines for Malaria Venture

NMCP : National Malaria Control Program

Pyr-As : Pyronaridine-Artesunate

SMC : Seasonal Malaria Chemoprevention

SMQ : System of Management of the Quality

USTTB : Université des Sciences, des Techniques et des Technologies de Bamako

TBV : Transmission Blocking Vaccine

PREAMBULE

This document is the annual activity report of the Groupe de Recherche Action en Santé (GRAS), outlining the initiatives taken, the objectives and the results obtained during the year 2020 in accordance with the annual work plan of the Institute.

The year 2020 has been a pivotal year in the pursuit of excellence for the Groupe de Recherche Action en Santé (GRAS). Several health programmes, whose ultimate goal is to contribute to the improvement of the health of populations, were implemented. The year was especially marked by the creation of GRAS as a research institute under private law in human health by the Ministry of Higher Education, Scientific Research and Innovation (MHESRI).

It is with great satisfaction that we welcomed this affiliation which is the culmination of a long process. Together, with a multidisciplinary and competent team, we are working daily according to our vision of becoming a center of excellence in biomedical and operational research in West Africa.

The results of our research have helped to guide policy makers in improving the health system. In this sense, GRAS has had the privilege of conducting a clinical trial on a candidate vaccine against typhoid fever in children, the results of which serve as a basis for advocacy for its introduction into the Expanded Programme on Immunisation (EPI) in Burkina Faso.

Dr Sodiomon B. SIRIMA, MD, BA, PhD



Chief Executive Officer
Knight of the National Order

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Introduction

Improving the health and living conditions of the population, especially of vulnerable groups, is a major concern for the Groupe de Recherche Action en Santé. GRAS is a legally recognised human health research institute whose ambition is to be a centre of excellence in the field of health research.



It works according to well-defined missions and according to a vision. In the implementation of its activities, GRAS has signed a collaboration agreement with the Ministry of Health of Burkina Faso. During the year 2020, GRAS conducted various research studies.

It should be noted that the current context of the COVID-19 pandemic, which has been raging since the first quarter of 2020, has led to readjustments in the implementation of GRAS activities during the year. As an immediate consequence, some activities initially planned to start in 2020 were not able to start effectively.



1. PRESENTATION OF GRAS

GRAS is a research institute under private law in Burkina Faso accredited by the MHESRI in the field of human health research, under the reference "N°2020/661/MESRSI/SG/DGRSI of 24/06/2020". It intends to play an important role in the conduct of key and innovative health studies, with a view to generating new evidence-based knowledge, providing guidance to policy makers and study sponsors.

Its main tasks are:

- to conduct biomedical and clinical research and implementation studies to meet the medical needs of patients and populations in developing countries;



- to strengthen the skills of health research professionals through training and assistance to teams in the conduct of clinical research;

- to satisfy the needs and expectations of clients and relevant stakeholders by implementing a quality approach in accordance with ISO 9001 version 2015 standards.

GRAS has its headquarters and central laboratory in Ouagadougou, located in the Somgande district (sector 29). It has satellite sites in urban areas (Schiphra Hospital), semi-urban areas (Medical Centre with surgical branch in Banfora) and rural areas (Medical Centre with surgical branch in Sabou).

2. GRAS COOPERATION AGREEMENT

2.1. Collaboration agreement with the Ministry of Health

An agreement between the Ministry of Health and GRAS for the implementation of health promotion activities in Burkina Faso was established on 12 September 2019. It allows GRAS to carry out its activities throughout the national territory.

Thus, through the signing of this agreement, GRAS undertakes:

- to abide by the health policy of Burkina Faso;
- to send a quarterly and annual report on health activities to the districts and regional health directorates of its intervention zones
- to provide the Ministry of Health with an annual health activity report, as well as its annual activity programme.

2.2. Other collaboration agreements

In addition to the Ministry of Health, GRAS has also signed collaboration agreements with public and private structures working in the field of human health.

These include :

- the National Centre for Scientific and Technological Research;
- the Saint Maximillian Kolbe Medical Centre in Sabou;
- the Health District of Sabou ;
- the Health District of Banfora
- the Schiphra Hospital in Ouagadougou;
- the Higher Institute of Population Sciences.



3. 2020 PHYSICAL ASSESSMENT

3.1. Review of research and training projects carried out during 2020

3.1.1 GRAS staff

The GRAS team is multidisciplinary, including epidemiologists, clinical trialists, physicians, pharmacists, biologists, sociologists, data managers, research assistants, administrative staff, nurses and support staff.



Table 5: *Status of GRAS staff*

Staff	Number of employees	Percentage
Regular staff	50	73.5%
Research Associates/Part time workers	18	26.5%
TOTAL	**68**	**100%**

3.1.2 Research and training activities

During the year 2020, GRAS implemented 16 research and training projects (Table 2 and 3) focusing mainly on malaria and diarrhoeal diseases.

- ❖ In the framework of the fight against malaria, the following activities were carried out:
  - malaria vaccines: two vaccine trials, two baseline studies to prepare sites for malaria vaccine trials and a study to select future vaccination sites were implemented ;
  - antimalarial treatment: studies on new antimalarial



drugs and the optimisation of the use of current antimalarial treatments in order to strengthen the health system in the management of malaria have been conducted ;

- basic research focused on seasonal malaria chemoprevention, malaria susceptibility in Fulani and Mossi ethnic groups and the interaction between malaria and Covid-19.



- ❖ Vaccines against diarrhoeal diseases and urinary schistosomiasis: These included the publication of typhoid fever vaccine trial data and the start of the Shigella baseline study to generate important data on the disease in preparation for a vaccine trial. Preparatory activities for the conduct of a schistosomiasis vaccine trial were also carried out.
- ❖ Training on good practice in data and management of students.

Table 6 *: Progress report on the implementation of 2020 research projects*

	Number of projects planned	**Number of projects carried out**	**Rate of achievement**
Research projects	16	14	87%

Table 3 provides a summary of the activities carried out by GRAS during the year 2020. (*See the following pages*)

Table 7 : list of projects for the year 2020

N°	Project title	Collaborators / partners	Sources of funding
Projects closed in 2020			
1	Multilateral initiative to accelerate the clinical development of effective malaria vaccine candidates in Africa (MMVC)	University of Oxford; United Kingdom Institut de Recherche en Science de la Santé (IRSS).	European and Developing Countries Clinical Trials Partnership (EDCTP) 2
2	Dose escalation study of Sanaria's irradiated sporozoite vaccine (PfSPZ Vaccine), followed by a randomized, double-blind, placebo-controlled Phase 1 clinical trial to evaluate the safety and immunogenicity of PfSPZ Vaccine in malaria-experienced adults in Burkina Faso. (PfSPZ)	University of Maryland School of Medicine; Sanaria ; Crucell ; Howard Hughes Medical Institute.	DMID/NIH
3	The role of microRNA (miRNA) in malaria resistance/susceptibility in Peulh and Mossi ethnic groups in a hyper-endemic area of Burkina Faso (miARN).	Sapienza / University of Roma University of Bamako.	University Sapienza of Roma
4	A Phase 2 Randomized, Double-Blind, Controlled Trial of the Safety and Immunogenicity of Typhoid Conjugate Vaccine (Vi-TCV) among Children Younger than 2 Years in Ouagadougou, Burkina Faso (TyVAC).	University of Maryland School of Medicine; Center for Vaccine Development and Global Health.	Bill and Melinda Gates Fundation
5	Internal courses on good data management practices.	World Health Organisation (WHO)	WHO

Projects started in 2020			
1	Age de-escalation study to assess safety and immunogenicity of recombinant E. coli BK-SE36 malaria vaccine candidate formulated with CpG adjuvant administered intramuscularly in healthy malaria exposed African adults and children living in Burkina Faso (SEMALVAC 2).	Nobel Pharma, University of Osaka ; European Vaccine Initiative (EVI) in Germany; Institut de Recherche en Science de la Santé (IRSS), Hôpital Schiphra de Ouagadougou.	Global Health Innovative Technology (GHIT) Nobelpharma Co.
2	Preparatory Phase II for the NPC-SE36/CpG malaria vaccine candidate (SEMALVAC 4).	Nobel Pharma, University of Osaka; European Vaccine Initiative (EVI) en Allemagne; Research Institute for microbial diseases.	Global Health Innovative Technology (GHIT)
3	Baseline cohort study to assess the malaria morbidity in children living in future malaria vaccine candidate trial site of Burkina Faso - MIMVaC- Africa (BLOOMY).	Ifakara Health Institute Trust (IHI), Tanzania; Centre de Recherches Médicales de Lambaréné (CERMEL), Gabon ; Fundação Manhiça (FM), Mozambique ; Eberhard Karls Universität Tübingen (EKUT), Germany ; University of Oxford, United Kingdom ; EVI, Germany ; Academisch Ziekenhuis Leiden (LUMC), Netherland ; Luxembourg Institute of Health (LIH), Luxembourg ; Osaka University, Japan, Health District of Banfora.	European and Developing Countries Clinical Trials Partnership (EDCTP) 2
4	Community Dynamics of Malaria Transmission in Humans and Mosquitoes at the area of Sabou, Burkina Faso (CODYMAT).	Université des Sciences, des Techniques et des Technologies de Bamako (USTTB), Mali; Statens Serum Institut, Copenhague, Danemark; Centre National de Formation et de Recherche en Santé Rurale Jean SENECAL de Maferinyah, Guinée; National Public Health Institute of Liberia, Liberia; Stichting Katholieke Universiteit, Netherlands; PATH, USA, National Institute of Allergy and Infectious Diseases, USA ; , Health District of Sabou.	European and Developing Countries Clinical Trials Partnership (EDCTP) 2

5	Phase 2 and 3 trial to evaluate the safety and efficacy and transmission blocking properties of the new antimalarial drug KAF156 and lumefantrine (WANECAM 2).	Université des Sciences, des Technique et des Technologies de Bamako (USTTB), Mali ; Centre de Recherches Médicales de Lambaréné (CERMEL), GABON : Institut des Sciences et Techniques de Bobo (INSTech-Bobo), Burkina Faso ; Universite Abdou-Mounouni de Niamey, Niger ; London School of Hygiene & Tropical Medicine, United Kingdom; University of Tübingen, Germany; Karolinska Institutet Stockholm County, Sweden; Amsterdam UMC, Netherlands; Université Claude Bernard Lyon1, France.	European and Developing Countries Clinical Trials Partnership (EDCTP) 2
6	Portfolio approach to developing the next-generation of malaria treatments for Africa (PAMAfrica).	Novartis ; Medicines for Malaria Venture (MMV) Institut de Recherche en Science de la Santé (IRSS) : Fundação Manhiça (FM), Mozambique ; Eberhard Karls Universität Tübingen (EKUT), Barcelona Institute for Global Health; Lambaréné Medical Research Center (CERMEL): Infectious Diseases Research Collaboration (IDRC).	European and Developing Countries Clinical Trials Partnership (EDCTP) 2
7	To assess the feasibility, acceptability and costs of multiple first-lines artemisinin-based combination therapies for uncomplicated malaria in the Kaya health district, Burkina Faso (MFT).	Medicines for Malaria Venture (MMV), Geneva, Switzerland; National Malaria Control Program (NMCP), Burkina Faso; IRSS, Burkina Faso.	Medicines for Malaria Venture (MMV)
8	Impact of seasonal malaria chemoprevention on the development of protective immunity and protection against clinical malaria in Burkina Faso (ISCHEMIC).	Kemri-Welcome Trust research program, Kilifi, Kenya; Karolinska Institut, Sweden ; Stockholm University, Sweden; Health District of Sabou.	European and Developing Countries Clinical Trials Partnership (EDCTP) 2

9	Malaria as a risk factor for COVID-19: a cross-sectional survey and an all-age clinical and immunological cohort study in Burkina Faso (MALCOV).	liverpool school of tropical medicine (LSTM), United Kingdom; London School of Hygiene & Tropical Medicine (LSHTM); Kemri-Welcome Trust research program, Kilifi.	Bill and Melinda Gates Fundation
10	A baseline Study in Support of Clinical Evaluation of an Oral Shigella Vaccine development in Africa. (SHIGORAVAX).	European Vaccine Initiative (EVI), Germany; University of Gothenburg (UGOT) Gothenburg, Sweden; Leiden University Medical Centre, Netherlands; Centre for Infectious Disease Research in Zambia (CIDRZ), Lusaka, Zambia; MSD Wellcome Trust Hilleman Laboratories, India.	European and Developing Countries Clinical Trials Partnership (EDCTP) 2
11	Phase I clinical trial of Smp80-GLASE candidate vaccine (SchistoShield®) in adults of endemic areas of sub-Saharan Africa (VASA).	The Chancellor Masters and Scholars of the University of Cambridge, United Kingdom; Academisch Ziekenhuis Leiden, Netherlands; Goeteborgs Universitet, Sweden; Eberhard Karls Universitaet Tuebingen, Germany; University of Antananarivo, Madagascar; University of Ouagadougou, Burkina Faso; Texas Tech University, USA; PAI Life Sciences Inc, USA; International Vaccine Institute, South Corea	European Union (UE)

3.1.2.1 Malaria vaccine developments

3.1.2.1.1 SEMALVAC 2 Study

SEMALVAC 2 : Age de-escalation study to assess safety and immunogenicity of recombinant E. coli BK-SE36 malaria vaccine candidate formulated with CpG adjuvant administered intramuscularly in healthy malaria exposed African adults and children living in Burkina Faso.

As part of the development of effective malaria vaccines, an ongoing Phase Ib clinical trial was completed by GRAS during 2020. This is a clinical trial of decreasing age to assess the safety and immunogenicity of the blood phase recombinant malaria vaccine candidate, BK-SE36.

The aim of the study is to evaluate the safety and reactogenicity of 3 doses of the malaria vaccine candidate BK-SE36 (100µg of SE36 protein + aluminum hydroxide gel).



This study took place at Schiphra Hospital from 2018 to 2020, where 135 participants included in 3 different cohorts, were vaccinated according to the study procedures. This was a phase Ib controlled, randomised, double-blind clinical trial staggered over participants of decreasing age. Cohort 1 consisted of adults aged 21-45 years (n=45), cohort 2 of children aged 5-10 years (n=45) and cohort 3 of children aged 12-24 months (n=45). Recruitment and follow-up of study participants was completed in 2019. During 2020, the main activities related to this research project were the management of the study data.

3.1.1.1.1 SEMALVAC 4 Study

SEMALVAC 4 : Preparatory Phase II for the NPC-SE36/CpG malaria vaccine candidate

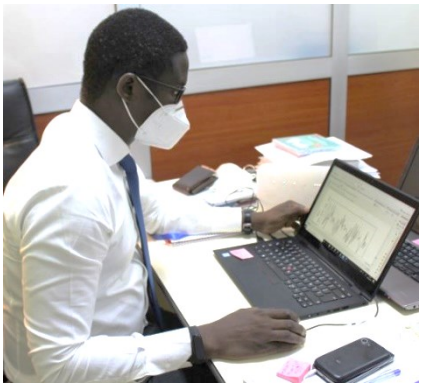
BKSE36 is a blood-stage vaccine candidate that has shown promising results in a Phase Ia trial in Japanese adults not exposed to malaria, as well as in Phase Ib trials in healthy subjects in malaria-endemic areas. The promising results of the trial justified a study site selection in Africa to conduct a large Phase 2 efficacy study. The activity could not start in 2020 due to the Covid-19 pandemic.

3.1.1.1.2 PfsPZ Study

PfSPZ : Dose escalation study of Sanaria's irradiated sporozoite vaccine (PfSPZ Vaccine), followed by a randomized, double-blind, placebo-controlled Phase 1 clinical trial to evaluate the safety and immunogenicity of PfSPZ Vaccine in malaria-experienced adults in Burkina Faso

Plasmodium falciparum sporozoite Vaccine (PfSPZ Vaccine), a vaccine using the entire parasite, has been shown to be safe and protective for six months in Malian adults receiving a five-dose schedule.

We conducted a double-blind, randomised, placebo-controlled trial in healthy adults in Burkina Faso. Participants were randomized to receive either three doses of vaccine or normal saline.



The main objective was to determine the safety and efficacy of the malaria vaccine within six (6) months of vaccination. The study has been completed, and activities during the year 2020 included data cleaning and writing the research results.

3.1.1.1.3 BLOOMY Study

BLOOMY : Baseline cohort study to assess the malaria morbidity in children living in future malaria vaccine candidate trial site of Burkina Faso

In the fight against malaria, the development of an effective malaria vaccine is crucial in view of the continued high transmission of malaria, increasing drug and insecticide resistance, and the often inadequate coverage of current control interventions. In addition, there is growing concern that immune responses to malaria vaccine candidates may be impaired by malaria-induced immunosuppression prior to vaccinations (with vaccine candidates under study); therefore, pre-treating individuals prior to vaccination in malaria-endemic areas deserves close attention.

In preparation for Phase 2b clinical trials of the malaria vaccine, this baseline study was conducted to determine the incidence of malaria after radical treatment with effective antimalarials in a population of 1.5-12 years of age for which these critical data are lacking.

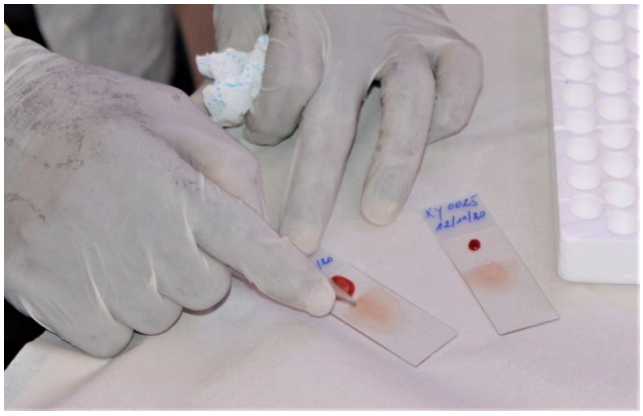


The study was conducted in the health district of Banfora, located in the Cascades region. During the year 2020, the study activities consisted first of community information and sensitisation meetings to get the communities on board. Then, a total of 490 children aged 18 months to 12 years were enrolled during the screening visit. These volunteers received malaria treatment with Artesunate monotherapy for 7 days or Dihydroartemisinin-Piperaquine for 3 consecutive days. Participants were enrolled in the cohort, 21 days after treatment. 464 participants were included in the cohort for a longitudinal follow-up of 6 months. Two approaches were used to collect data for the evaluation of the study objectives. These were active follow-up every 2 weeks at the participant's home and passive follow-up at the health centre. Participant follow-up activities continue in 2021.

3.1.1.1.4 CODYMAT Study

CODYMAT : Community Dynamics of Malaria Transmission in Humans and Mosquitoes at the area of Sabou, Burkina Faso

improved Evaluation tests are needed to measure vaccine efficacy. Transmission blocking vaccines (TBVs) work by inducing antibodies that inhibit parasite development in the mosquito, interrupting transmission. Vaccine efficacy can be estimated by in vitro membrane blood meal tests using immune sera and laboratory mosquitoes. But qualified tests that measure transmission in the field are needed to evaluate transmission-blocking interventions in the real world.



The aim of the study is to estimate the rate of malaria transmission as measured by the capture of live mosquitoes in the wild, by locality, year and season.

The study is taking place in the Sabou health district located in the Centre West region. Community meetings with the presentation of the study objectives and procedures were conducted in the last quarter of 2020.

Recruitment of participants will continue during 2021. Participants, parents/guardians of participants aged 0.5 to 65 years will be approached to participate in the study. Enrolled subjects will be visited monthly. During these visits, thick blood drops will be taken; and live and dead mosquitoes (by spraying) will be captured in/around the homes. Each individual will be followed up to one year, in order to collect data that will be used to select the type of study to be conducted in future community trials of VBT.

3.1.1.1.5 MMVC Study

MMVC : The Multi-Stage Malaria Vaccine Consortium (Consortium pour un vaccin contre le paludisme)

A highly effective malaria vaccine is urgently needed to reduce the unacceptable burden of malaria in Africa and eliminate malaria. An ideal vaccine must target all stages of the parasite's life cycle, but no such vaccine has yet been tested in Africa. MMVC will test a multi-stage vaccine in a large phase IIb efficacy trial in infants in West and East Africa.

Preparatory meetings for the different phases of the study continued during the year 2020

3.1.1.2 Development of antimalarial drugs

3.1.1.2.1 WANECAM 2 Study

WANECAM 2 : West African Network for Clinical Trials of Antimalarial Drugs

Artemisinin-based combination therapies (ACTs) are the cornerstone of the malaria control and elimination strategy. However, increasing resistance to artemisinin derivatives is now a growing problem in South East Asia. In Africa, although artemisinins remain effective, the failure of ACTs due to resistance to related drugs is also a concern. Therefore, it is important to develop new antimalarial drugs of new classes that can stop resistance.



KAF156, an imidazolepiperazine, is one of the leading antimalarial candidates in development. It is a new drug developed by Novartis. Its structure and mode of action are different from currently marketed antimalarial drugs and other antimalarial drug candidates.

The new combination of KAF156 with LUM-SDF is expected to be fast-acting and fully curative, improving patient compliance and potentially reducing malaria transmission.
This study aims to determine the efficacy, safety and tolerability of the investigational drug in patients aged 6 months to <18 years with uncomplicated *P. falciparum* malaria.

The activities of obtaining the regulatory authorisations for the conduct of the study, training and equipment were conducted during the year 2020.

3.1.1.2.2 PAMAFRICA Study

PAMAfrica : Portfolio approach to developing the next-generation of malaria treatments for Africa

Recent World Health Organization reports on malaria eradication have made it clear that defeating malaria will require new tools, including new and better medicines. The WHO World Malaria Report 2019 indicates that global malaria deaths are declining at a slower rate compared to recent years and highlights the need for improved interventions to treat the most vulnerable populations, including babies. The objective of this first study is to develop the first new malaria treatment for babies under 5 kg, a new formulation of Coartem®.



The activities of obtaining regulatory authorisations, training and equipment purchase were carried out during the year 2020.

3.1.1.2.3 MFT study

MFT : To assess the feasibility, acceptability and costs of multiple first-lines artemisinin-based combination therapies for uncomplicated malaria in the Kaya health district, Burkina Faso

As part of the strengthening of the health system in Burkina Faso, a study on the optimisation of the use of current antimalarial drugs was conducted in the health district of Kaya. This involved the simultaneous deployment of several first-line treatments for uncomplicated malaria using artemisinin-based combination therapies. Theoretical models have shown that this strategy can extend the useful therapeutic life of current ACTs by reducing drug pressure and slowing the spread of resistance without endangering patients' lives. Thus, a simultaneous deployment of three ACTs, Artemether-Lumefantrine (AL), Pyronaridine-Artesunate (Pyr-AS) and Dihydroartemisinin-Piperaquine (DHA-PQ), targeting three segments of the population was conducted.

The aim of this study is to assess the feasibility, acceptability, costs and effects of the MFTs pilot study on the treatment of uncomplicated malaria in the health district of Kaya. The study is divided into four phases: the formative phase, the deployment phase, the monitoring/evaluation phase and the post-evaluation phase.



The formative phase consisted of cascading training sessions for the actors involved. In total, 253 health workers in the Kaya district were trained in the study procedures. The implementation of the strategy with the deployment of the three (3) ACTs took place from 02 December 2019 to 01 December 2020.

The monitoring and evaluation phase made it possible to collect data for the evaluation of the programme indicators. The programme as a whole covered 40 out of 43 health facilities. A total of 183,800 cases of uncomplicated malaria were diagnosed in the district health facilities in 2020 and 182,247 malaria episodes were treated with ACTs. For the

treatment of malaria with ACTs, 44.5%, 49.1% and 6.4% of uncomplicated malaria episodes were treated with Pyr-AS, DHA-PQ and AL, respectively.

The quantitative household survey was conducted among 1,036 households to assess care-seeking practices and attitudes and the acceptability of ACTs during the implementation of the programme. For the qualitative surveys, 33 focus group interviews and 28 individual in-depth interviews were conducted with all health system stakeholders.

3.1.1.3 Fundamental research on malaria

3.1.1.3.1 ISCHEMIC Study

ISCHEMIC : Impact of seasonal malaria chemoprevention on the development of protective immunity and protection against clinical malaria in Burkina Faso

Basic research was one of the main activities of GRAS during the year 2020. A study on seasonal malaria chemoprevention (SMC) called ISCHEMIC was conducted in the Sabou health district. SMC consists of a monthly full dose of sulfadoxine-pyrimethamine plus amodiaquine treatment for children aged 6-59 months for 4 months from July to October corresponding to the high malaria transmission season. However, it is not clear whether there is a cumulative effect of SMC over time on the acquisition of immunity to the malaria parasite.



This pilot study was conducted to establish key elements for understanding the potential role of SMCs in enhancing immunity and protection against clinical malaria. It was a cohort study following the national policy on SMC in Burkina Faso.

The study was conducted in several phases: community meetings and recruitment and follow-up of participants. The children included in the study were followed for six (6) months covering the periods of the cross-sectional surveys (CS). Indeed, five (5) cross-sectional surveys were conducted at one-month intervals from July-December 2020.

3.1.1.3.2 mi ARN Study

mi ARN : The role of microRNA (miRNA) in malaria resistance/susceptibility in Peulh and Mossi ethnic groups in a hyper-endemic area of Burkina Faso.

Subjects from the Fulani ethnic group express a strictly different immune response to P. falciparum malaria than the Mossi ethnic group living in sympatry. These two ethnic groups, whose genetic and cultural backgrounds are well differentiated, live in the same conditions of hyper-endemic transmission in the Sudanese savannah zone north-east of Ouagadougou.



The aim of the study is to contribute to the characterization of B-cell and miRNA transcriptomes of serum and PBMCs (peripheral blood mononuclear cells) of individuals from the Fulani and Mossi ethnic groups in Burkina Faso. During the year 2020, activities focused on the analysis and publication of data.

3.1.1.3.3 MALCOV Study

MALCOV: Malaria as a risk factor for COVID-19: a cross-sectional survey and an all-age clinical and immunological cohort study in Burkina Faso.

While knowledge about the risk factors for COVID-19 in developed countries is rapidly evolving, less is known about the risk factors in malaria-endemic countries. It is not known whether malaria exacerbates COVID-19, affects the acquisition of protective antibodies against SARS-CoV-2, or contributes to its further spread by leading to a higher viral load and longer duration of viral shedding.



The relationship may be complex, as chronic malaria may result in a hypo-response of the immune system, which in some cases may be protective if it dampens some of the potentially lethal excessive immune responses associated with severe COVID-19.

It is also unknown whether effective treatment of malaria alters any of these potential associations. The aim of the study is to determine whether antimalarial drugs, such as pyronaridine, have a positive, negative or non-negligible effect on the immune response to COVID-19.

The start of the activities was delayed due to difficulties in obtaining some equipment because of the Covid-19 pandemic.

3.1.1.4 Control of diarrhoeal diseases and schistosomiasis

3.1.1.4.1 SHIGORAVAX Study

SHIGORAVAX : A baseline Study in Support of Clinical Evaluation of an Oral Shigella Vaccine development in Africa.

In the framework of the fight against diarrhoeal diseases, GRAS initiated in 2020, a large programme aiming at the implementation of an effective and well-tolerated oral vaccine against shigellosis (bacillary dysentery) in children under five (5) in Burkina Faso and Zambia called ShigOraVax study.

The first phase of the programme was the conduct of a baseline epidemiological study with the main objective of generating data on the burden of shigellosis and circulating strains of shigella in the areas where the future clinical trials will be conducted.



The study is taking place in the health district of NongrMassom, located in the Centre region, at two sites (Nioko and Polesgo). It consists of two phases: Phase I, consisting of household identification, recruitment of participants and collection of baseline data; and Phase II, consisting of active and passive follow-up of the participants included.

During the year 2020, the main activities carried out are community sensitisation, enrolment and follow-up of participants.

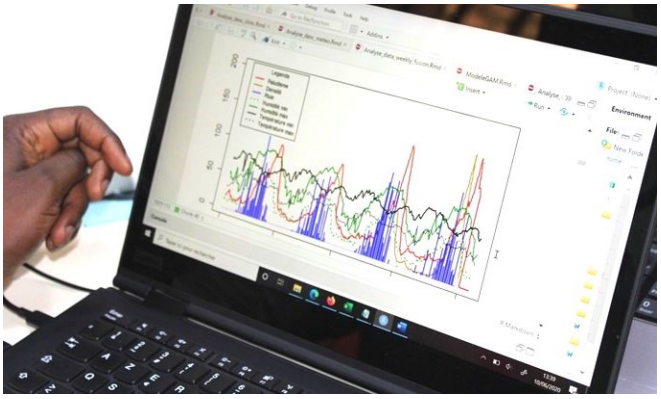
3.1.1.4.2 TyVAC Study

TyVAC : A Phase 2 Randomized, Double-Blind, Controlled Trial of the Safety and Immunogenicity of Typhoid Conjugate Vaccine (Vi-TCV) among Children Younger than 2 Years in Ouagadougou, Burkina Faso

The World Health Organization (WHO) pre-qualified a single-dose Typhoid Vaccine Conjugate (Typbar TCV®, Bharat Biotech International) in 2018 and identified co-administration as a research priority. We conducted a trial on co-administration of Typbar TCV® with measles-rubella and yellow fever vaccines at nine (9) months; and measles-rubella and meningococcal group A (MCV-A) vaccines administered at 15 months in Burkina Faso.

This was a randomised, double-blind, controlled, phase II trial. The results showed that Typbar TCV® can be safely co-administered at nine (9) and 15 months of age with routine EPI vaccines.





These data support widespread adoption in sub-Saharan Africa. Dissemination of the study results and advocacy for the introduction of typhoid fever vaccine were conducted in 2020.

3.1.1.4.3 Etude VASA

VASA : Phase I clinical trial of Smp80-GLASE candidate vaccine (SchistoShield®) in adults of endemic areas of sub-Saharan Africa

Schistosomiasis is a neglected poverty-related tropical disease that affects one billion people in 74 countries. Medical treatment is the currently available method of controlling schistosomiasis, but the effectiveness of mass treatment programmes is compromised by reinfection requiring regular treatment.

An effective vaccine, with long-lasting protection against all forms of schistosomiasis, would have an impact on disease control. The aim of the present study is to evaluate the safety/immunogenicity of the SchistoShield® vaccine (Sm-p80 antigen + GLA-SE adjuvant) in a phase I clinical study in healthy African adults.



Activities in 2020 consisted of preparatory meetings and procurement of materials.

3.2 Specific activities

During the year 2020, GRAS also carried out specific activities (Table 4) such as training, strengthening its quality management system and renovating its infrastructure.



3.2.1 Training activities

These are the supervision of Master's and doctoral specialisations and the strengthening of the capacities of its staff, through continuous training.



In addition, as part of its missions, GRAS researchers have provided teaching in university Masters courses for the benefit of students. A series of training sessions on good data management practices were also given to research actors in Burkina Faso.

3.2.2 Strengthening the system of management of the quality

In order to build a reference research structure, GRAS has launched the implementation of system of management of the quality (SMQ) with a view to certification under the ISO 9001V2015 standard.



Throughout the year 2020, the Association Burkinabè pour le Management de la Qualité (ABMAQ) has accompanied GRAS through a quality diagnostic audit, the development and implementation of the QMS.

The ultimate goal is to set up and maintain a quality management system, following the recommendations of the ISO 9001V2015 standard. ISO 9001V2015 is an international standard that sets out the requirements for a SMQ. The main activities during the year 2020 were the identification, mapping and drafting of processes within the framework of the SMQ.

3.2.3 Infrastructure upgrades

These are the GRAS headquarters and the central laboratory with an R+3 building. Renovation work on the GRAS satellite sites based in the health districts of Sabou and Banfora also began in 2020.





3.2.4 Other specific activities.

These are :

- publications in scientific journals;
- participation in scientific conferences and congresses
- expert committees and scientific committees;
- Reading committees of national or international scientific journals.





Table 8 *: Summary of specific activities*

Headline	2019	2020
Training of GRAS personnel		
Master	0	3
PhD	1	1
Training delivered by GRAS for the benefit of students		
Master in Molecular Biology	0	2
Scientific publications		
Papers in scientific journals	8	7
Presentations at conferences	2	3

Conclusion

GRAS, as a human health research organisation, remains an essential instrument for accompanying and guiding health policies and programmes in Burkina Faso.

The portfolio of activities for 2021 will allow GRAS to position itself on the chessboard of reference research organisation in Burkina Faso.

The results of studies conducted by GRAS could guide political decision-makers in making decisions to improve the health of our populations.

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Burkina Faso

PNLP

INSP
Burkina Faso
Institut National de Santé Publique

IASP

06 BP 10248 Ouagadougou 06, Secteur 19, Somgandé,
Tél. : (+226) 25 35 56 90 Fax (+226) 25 35 56 73
Email : gras@fasonet.bf - Site web : www.gras.bf