

ANNUAL REPORT 2023



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Message from the Chairman and Executive Director

On 5 May 2023 the Director-General of the World Health Organization (WHO), Dr Tedros Ghebreyesus, officially declared an end to COVID-19 as a global health emergency. By then, the cumulative number of cases worldwide had reached more than 765 million, with nearly seven million deaths. Putting an end to the pandemic was a global collective effort using a multitude of public health measures, not at least a handful of highly effective vaccines. Despite initial hurdles in manufacturing enough vaccines and distributing them to the right places, an impressive 13.3 billion vaccine doses had been administered worldwide by the end of the pandemic. This is a testament to the important role of vaccines in global health, and an important reminder that vaccines can contribute immensely to the fight against infectious diseases, both during pandemics and in normal times.

Putting the pandemic behind us, European Vaccine Initiative (EVI) could once again fully focus its attention on the long-term goal of developing safe, effective and affordable vaccines for global health. Malaria remains one of the world's most devastating infectious diseases, both in terms of mortality and morbidity. It was therefore a significant milestone when WHO added R21/Matrix-M to its list of prequalified vaccines in December 2023. R21 is a pre-erythrocytic malaria vaccine, invented by University of Oxford and manufactured by the Serum Institute of India. It serves as a brilliant example of a vaccine that was developed through close collaboration between numerous academic and clinical teams across Europe, sub-Saharan Africa and globally. EVI has supported the development of R21 over many years, and EVI takes great pride in having contributed to its successful development. The year 2023 will therefore be remembered as an important year for R21 and EVI but it also marks the beginning of a new phase in the fight against malaria. **EVI will thus continue its support to R21 to make sure that it reaches its full potential through an optimised implementation.** R21 vaccine has so far been shown to be safe and effective for preventing malaria in children but EVI, together with its partners, hope to take it further and is now initiating clinical trials to extend its use to additional population groups.

One of these population groups is women of childbearing potential (WOCP), which are particularly neglected and vulnerable. EVI gives special attention to WOCP, which is underlined by our attempt to develop a vaccine targeting placental malaria. Throughout 2023, EVI has continued prepara-

tions and capacity building towards clinical efficacy testing in sub-Saharan Africa of a vaccine against VAR2CSA with the potential to prevent placental malaria.

In addition to malaria vaccine development, EVI has also continued its support to vaccine candidates against several other pathogens in 2023. This includes the pathogens causing diarrhoea, Leishmaniasis, and Nipah Virus Disease. In collaboration with Sumitomo Pharma Company, EVI has also initiated the preparation of the first clinical testing of a new universal influenza vaccine, which will start in 2024.

Throughout 2023 EVI has also continued its engagement in several projects for the development of new tools and technologies to support vaccinology in general. Coordinated by EVI, a new ambitious project, NOSEVAC, received funding from the European Union to develop new nasally administered vaccines. Meanwhile, the Inno4Vac consortium, a large public-private partnership that is funded by the Innovative Health Initiative (IHI) and coordinated by EVI has continued its efforts to develop new tools that may replace animal testing in early vaccine development. This is done through the refinement of several in vitro models, as well as through the development of new in silico models. In silico modelling is also being developed in another EVI-coordinated public-private partnership, PRIMAVERA, where an advanced model for the potential impact of vaccines against antimicrobial resistance is being developed.

Organisationally, EVI had the pleasure of welcoming Professor Samuel J McConkey as new Chair of the EVI Board in 2023. Professor McConkey is Head of the Department of International Health and Tropical Medicine and Deputy Dean at RCSI, University of Medicine and Health Sciences in Dublin, Ireland. Sam has previously served on EVI's scientific advisory committee, as well as representing RCSI, University of Medicine and Health Sciences on EVI's Board. Sam replaces Dr Clemens Kocken, who stepped down as Chair as his tenure came to an end and continues as vice-Chair. EVI would like to express its sincere gratitude to Dr Kocken for his visionary leadership and genuine dedication to the mission of EVI during his chairmanship.

Professor Samuel J McConkey, *Chair of the EVI Board*
Dr Ole F. Olesen, *Executive Director*

Vision

A world where vaccines create health and equity for all people

Mission

To develop new, safe, effective, and affordable vaccines for global health through collaboration and coordination

2023 in Highlights

Leading the next-generation **malaria vaccines**

Exploring novel strategies for **vaccine delivery**

Sustaining **TRANSVAC network**, Europe's vaccine development catalyst

Pioneering **intelligent use of vaccines** to tackle antimicrobial resistance

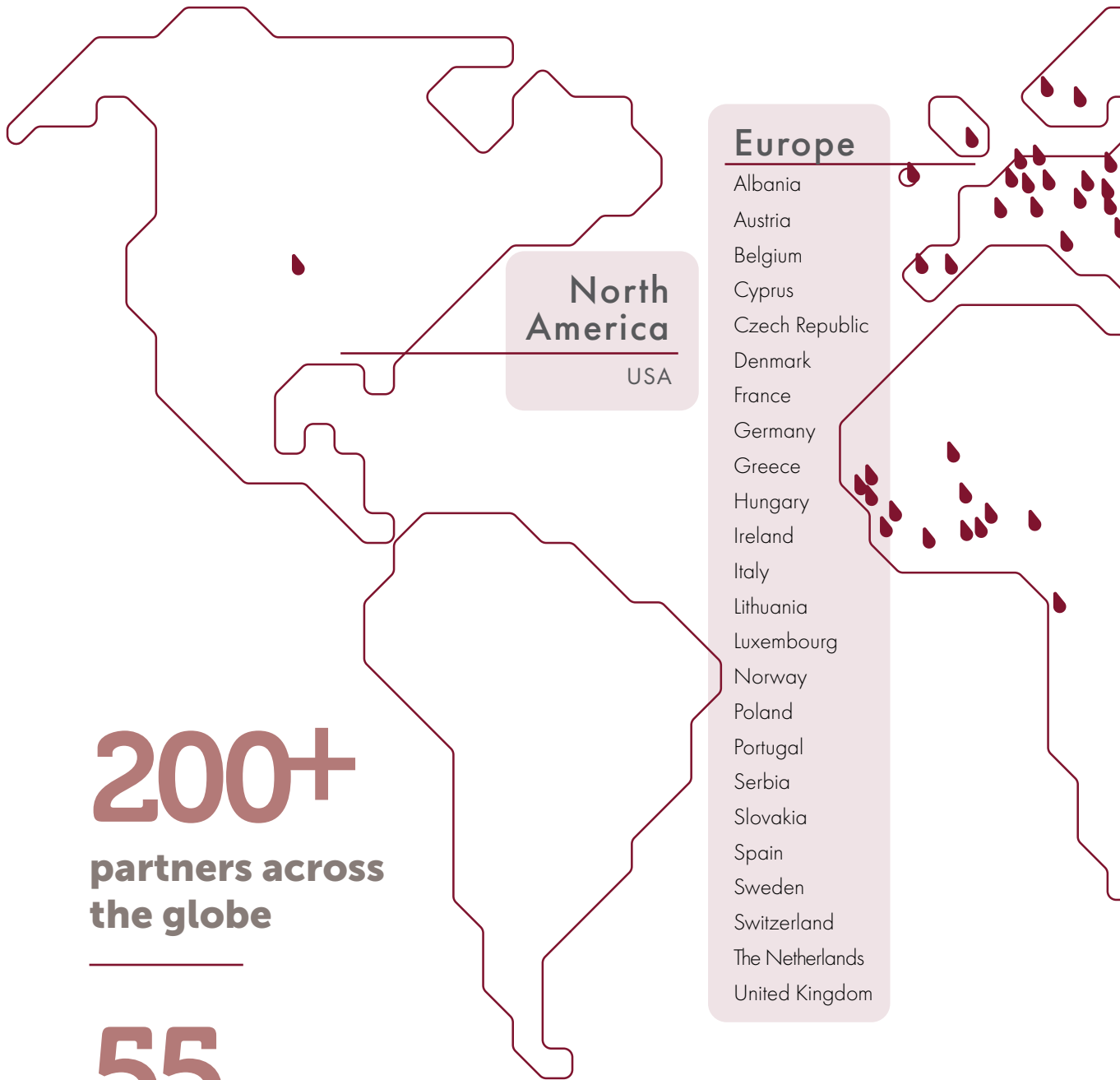
Delivering impactful **training in vaccinology**

Continuing development of a vaccine against **Nipah virus disease**

Protecting pregnant women from **malaria**



Global partners



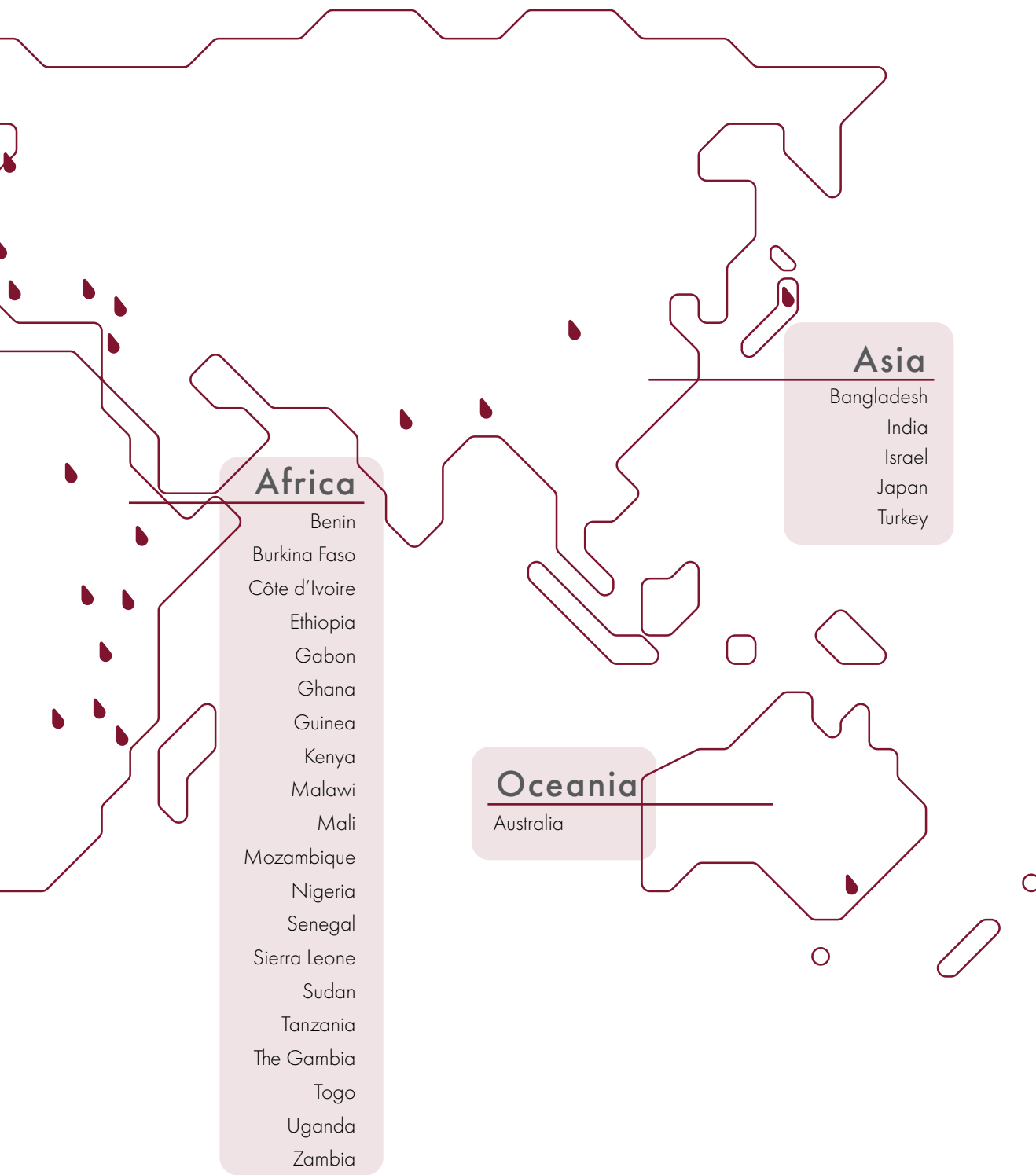
North America
USA

Europe

- Albania
- Austria
- Belgium
- Cyprus
- Czech Republic
- Denmark
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Lithuania
- Luxembourg
- Norway
- Poland
- Portugal
- Serbia
- Slovakia
- Spain
- Sweden
- Switzerland
- The Netherlands
- United Kingdom

200+
partners across
the globe

55
different countries



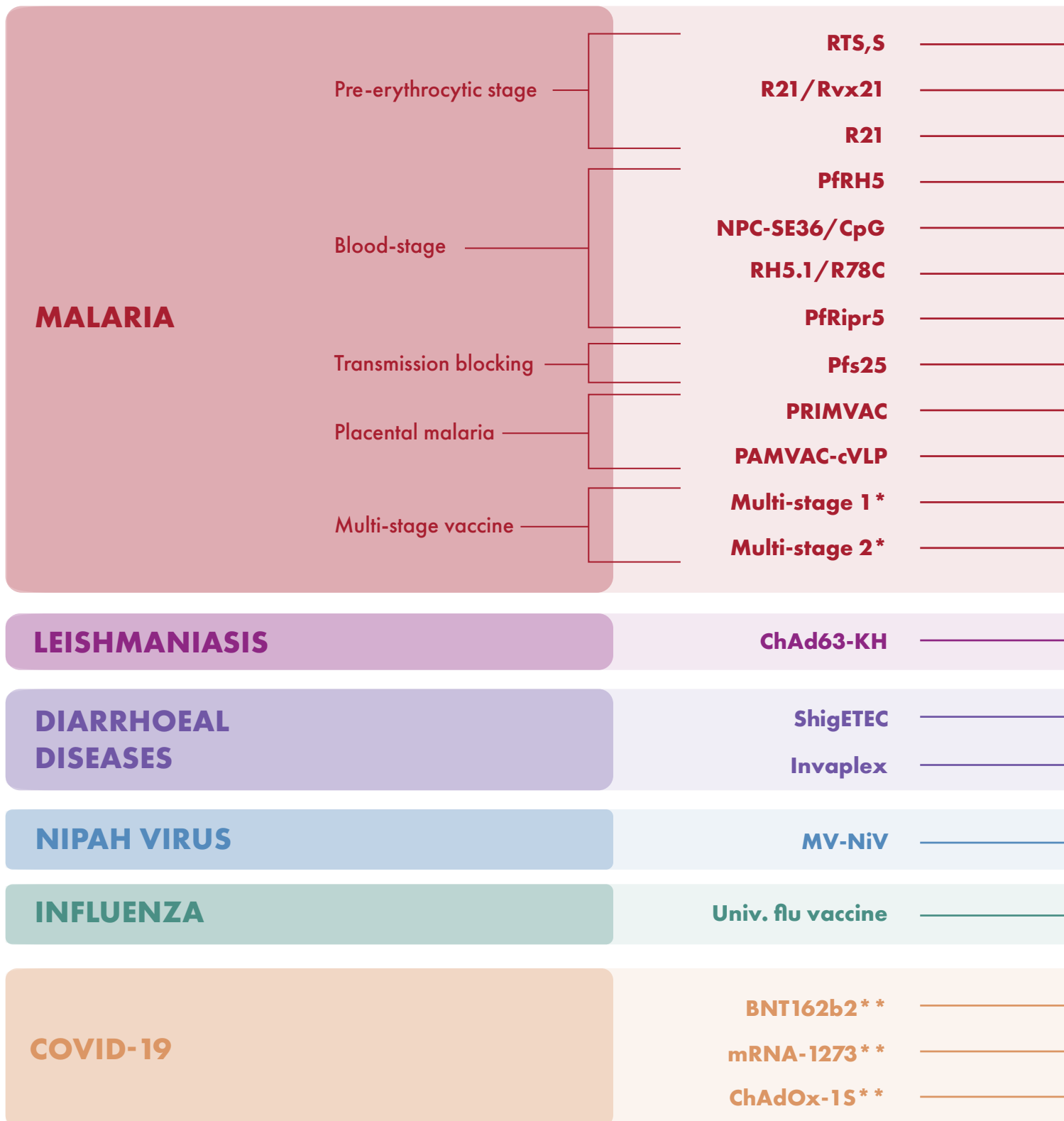
- Africa**
- Benin
 - Burkina Faso
 - Côte d'Ivoire
 - Ethiopia
 - Gabon
 - Ghana
 - Guinea
 - Kenya
 - Malawi
 - Mali
 - Mozambique
 - Nigeria
 - Senegal
 - Sierra Leone
 - Sudan
 - Tanzania
 - The Gambia
 - Togo
 - Uganda
 - Zambia

- Asia**
- Bangladesh
 - India
 - Israel
 - Japan
 - Turkey

- Oceania**
- Australia

Pipeline in 2023

Candidates



Current stage Funding secured

* Undisclosed combination

** Licensed vaccine assessed for alternative administration schedules

Preclinical

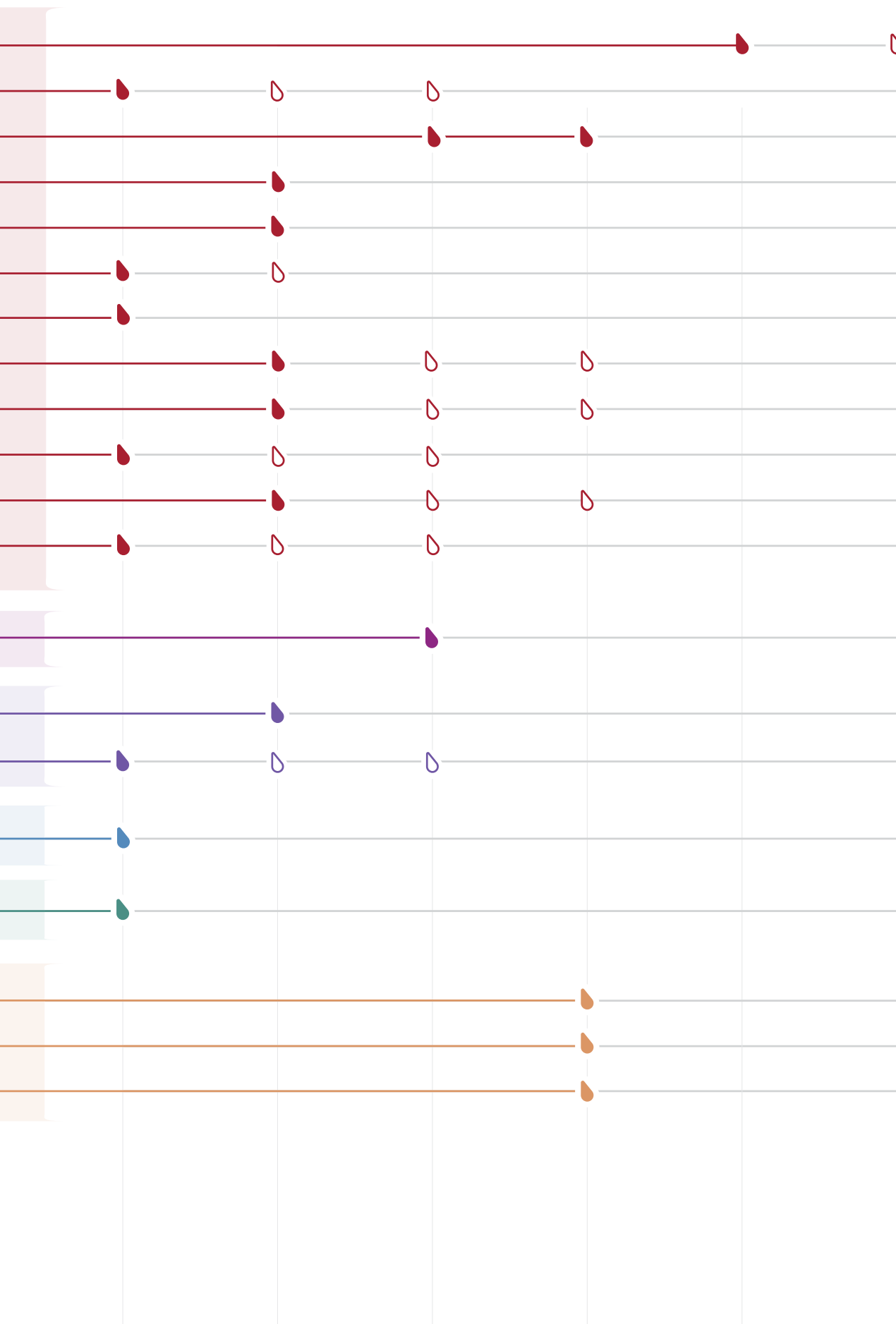
Phase I

Phase IIa

Phase IIb

Phase III

Phase IV



Malaria



Malaria is a life-threatening disease caused by *Plasmodium* parasites, transmitted to humans through the bites of infected female *Anopheles* mosquitoes. Among the five *Plasmodium* species that cause the disease, *P. falciparum* is the deadliest and most prevalent in sub-Saharan Africa, while *P. vivax* is the most geographically widespread, accounting for the majority of malaria cases in South America and South-east Asia.

Malaria presents as an acute febrile illness with common symptoms such as fever, chills, and headache. If left untreated, it can progress to severe complications like severe anaemia, cerebral malaria, and death.

Notably:

- **76%** of all malaria deaths occur in children under 5.
- There are **249 million** cases annually.
- **94%** of all cases occur in Africa.
- Approximately **43%** of the world's population is at risk.

Global efforts have halved malaria deaths between 2000 and 2019, but progress has since stalled, and every 2 minutes, a child still dies of malaria.

Malaria is both preventable and curable. Preventive methods include vector control, insecticide-treated nets, and intermittent preventive treatment during pregnancy and infancy. However, developing an effective malaria vaccine has been challenging due to the parasite's complex life cycle, its ability to evade the human immune system, and the genetic diversity of *Plasmodium* species. Current licensed vaccines have shown limited efficacy, highlighting the need for further research to enhance their effectiveness and achieve long-lasting immunity. Overcoming these challenges is essential to move closer to malaria eradication.

CHARTING A PATH TO A MALARIA-FREE WORLD THROUGH DIVERSE, NEXT-GENERATION VACCINE INNOVATIONS



Irene Nailain Nkumama
Malaria Programme Manager

What are the current obstacles in the fight against malaria, and why is there a pressing need for interventions like vaccines to achieve its eradication?

Malaria remains a significant public health challenge, affecting millions of people annually despite being preventable and curable. It exacerbates human inequity, predominantly impacting some of the world's lowest-income countries. Within these nations, the rural poor areas are most affected, and the majority of malaria fatalities occur among young children. This devastating impact persists despite substantial financial investment in malaria control, including the use of insecticides, bed nets, and drug treatments. New tools, particularly effective vaccines, are essential to transition from merely controlling the disease and reducing mortality to eliminating and eventually eradicating malaria.

The development and implementation of effective and safe vaccines are crucial for making significant strides towards the global goal of a malaria-free world.

Given the recent approval of two malaria vaccines, what is your perspective on the future direction of malaria vaccine development?

Thanks to tremendous collaborative efforts, there are now two licensed malaria vaccines, RTS,S/AS01 (Mosquirix™) and R21/Matrix-M, available for children living in areas with high or moderate malaria transmission. EVI supported the development of the R21/Matrix-M vaccine and remains committed to the implementation of the licensed vaccines.

Looking ahead, EVI aims to expand the use of the licensed vaccines to new population groups, while also developing next-generation malaria vaccines. This involves building a comprehensive portfolio that includes pre-erythrocytic, blood-stage, transmission-blocking and placental malaria vaccine candidates as well as combination malaria vaccines against both *P. falciparum* and *P. vivax* parasites. It also involves utilising novel vaccine platforms such as novel adjuvants and mRNA-LNP technology.

The future of malaria vaccine development is promising, with a multifaceted approach to enhance efficacy, broadening protection, and ultimately achieving malaria eradication. Continued innovation and collaboration are essential to fully realise the potential of these vaccines and address ongoing challenges in malaria control.

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Placental malaria

EMPOWERING WOMEN'S HEALTH: DRIVING PROGRESS WITH BREAKTHROUGH VACCINES AGAINST PLACENTAL MALARIA



Flavia D'Alessio
Senior Project Manager

How does placental malaria differ from other forms of malaria, and what unique challenges does this present for vaccine developers?

Placental malaria is a severe form of malaria caused by *Plasmodium falciparum* and predominantly affecting women during their first pregnancy. During pregnancy a different variant of the *P. falciparum* erythrocyte membrane protein 1 (PfEMP1) family, named VAR2CSA, is expressed by the infected erythrocytes, which enables adherence and accumulation of infected erythrocytes in the placenta, leading to severe complications such as maternal anaemia, cerebral malaria, abortion, stillbirth, low birth weight, and preterm delivery.

Protective immunity against placental malaria can be naturally acquired after successive pregnancies, supporting the idea that a safe and effective vaccine can be developed to protect pregnant women and their babies in endemic regions. The primary target group for a placental malaria vaccine is therefore women before they become pregnant for the first time. This would include women of childbearing age wishing to get pregnant and prepubescent and early pubescent girls. VAR2CSA is the leading vaccine antigen for placental malaria vaccines which are designed to induce inhibitory antibodies that prevent infected erythrocytes from binding to the placenta.

Major challenges in placental malaria vaccine development are to elicit a long-lasting immune response that remains protective when women get pregnant, and a broadly cross-inhibitory antibody response to overcome VAR2CSA genetic variation. The evaluation of placental malaria vaccine efficacy is also particularly complex due to the lack of suitable animal models and of surrogates of protection that could provide early indications of vaccine efficacy.

Why is it important to develop a specific placental malaria vaccine when a general malaria vaccine already exists?

The two licensed malaria vaccines, RTS,S/AS01 (Mosquirix™) and R21/Matrix-M are so far only approved for children, offer partial protection, and their efficacy in women of childbearing potential and/or pregnant women is unknown. It is therefore difficult to envisage how such vaccines could control placental malaria effectively. Pregnant women in endemic areas currently receive intermittent drug treatment, which starts too late to be fully effective and is hampered by increasing parasite resistance. A dedicated placental malaria vaccine would fill this critical gap, providing timely and effective protection for both pregnant women and their unborn children. While this form of malaria has been neglected by developers, EVI has been in the forefront of placental malaria vaccine development since 2004.

Through collaboration with research institutions across Europe and Africa, EVI has been instrumental in accelerating the development and clinical testing of two vaccine candidates targeting placental malaria, PRIMVAC and PAMVAC. Following promising results from previous phase Ia/Ib clinical trials, a comprehensive and multifaceted programme is now being implemented to advance their clinical development, evaluate novel delivery platforms and/or adjuvants to improve the vaccines' immunogenicity, perform a cost-effectiveness analysis and assess the feasibility and acceptability of introducing a placental malaria vaccine in endemic countries.

While this form of malaria has been neglected by developers, EVI has been in the forefront of placental malaria vaccine development since 2004.



Diarrhoeal diseases



Diarrhoeal diseases disproportionately affect disadvantaged communities due to inadequate sanitation, limited access to healthcare, and poor living conditions. It is the third leading cause of death in children under five, claiming around 440,000 young lives each year. Diarrhoeal diseases, caused by various pathogens including bacteria, viruses, and protozoa, spreads through contaminated food or water. Diarrhoeal disease cause severe dehydration and malnutrition while also significantly impacting community health and economic stability. Effective prevention is crucial to reducing the substantial morbidity and mortality associated with diarrhoea, but vaccine development faces challenges such as pathogen diversity, limited funding due to lack of commercial incentive, and the need for vaccines that are effective in resource-poor settings. Overcoming these obstacles is essential to reducing the burden of disease and improving global health equity.



The WHO has listed *Shigella* as a priority pathogen for the development of new vaccines, but despite decades of research there is currently no licensed vaccine available.



FROM LAB TO GLOBAL IMPACT: ACCELERATING VACCINE SOLUTIONS FOR DIARRHOEA



Sophie Houard
Director of Vaccine Development

What are the specific reasons for prioritising *Shigella* in the development of a diarrhoeal disease vaccine over other common pathogens?

Shigella should be prioritised in the development of a diarrhoeal disease vaccine for several key reasons. Firstly, *Shigella* is a major cause of moderate to severe diarrhoeal infections worldwide, responsible for an estimated 80–165 million cases each year, mostly in low or middle-income countries. Despite the use of antibiotics and improvement of sanitation, *Shigella* still causes between 28,000 and 64,000 deaths among children under 5 in lower-income countries annually. Secondly, *Shigella* infections are increasingly difficult to treat due to the rise of antimicrobial resistance (AMR). This pathogen has shown significant resistance to commonly used antibiotics, making it harder to manage and control outbreaks effectively. An effective vaccine against *Shigella* could substantially reduce the global burden of diarrhoea and combat the growing threat of AMR by reducing countries' reliance on antibiotics. The WHO has listed *Shigella* as a priority pathogen for the development of new vaccines, but despite decades of research there is currently no licensed vaccine available. EVI supports two *Shigella* vaccine candidates in early development in its portfolio. One is an intramuscular lipopolysaccharide-based vaccine Invaplex_{AR-deltox} associated with dmlT adjuvant that will be tested through the EDCTP-funded ShigaPlexIM project in a phase 1a/1b in European and African adults in 2024. The other vaccine candidate is an oral vaccine designed to prevent both *Shigella* and Enterotoxigenic *Escherichia coli* (ETEC) which, through the EU-funded SHIGETECVAX project, was tested successfully in European adults and has now entered an age-descending phase 1b clinical trial in adults, children and infants living in Bangladesh.

How can interdisciplinary collaboration be leveraged to overcome financial and logistical barriers in the development and distribution of vaccines for diarrhoeal diseases?

Interdisciplinary collaboration is pivotal in overcoming barriers in developing and distributing vaccines for diarrhoeal diseases. Involving local researchers fosters ownership and accelerates vaccine acceptance and rollout in endemic areas. This participation ensures that vaccines are tailored to local needs, enhancing their acceptance and effectiveness. Moreover, interdisciplinary teams can attract diverse funding sources and optimise logistics, from improving supply chains to enhancing cold storage capabilities and facilitating efficient distribution. Such a collaborative approach accelerates the introduction of vaccines and strengthens public health systems, ensuring sustainable impact in the fight against diarrhoeal diseases. Through strong collaboration between consortium partners from Europe, the USA, and Africa, preclinical and clinical immunology capacity is being strengthened and an infrastructure surveillance system for *Shigella* has been implemented in Burkina Faso and Zambia. In addition, by holding meetings and workshops, the feasibility of establishing a controlled human infection model (CHIM) for *Shigella* vaccine trials is being evaluated, and support for the initial steps needed to establish CHIM capabilities is being implemented in Burkina Faso and Zambia.

Pandemic threats



Pandemic threats are infectious diseases with the potential to cause widespread outbreaks, leading to severe illness, significant mortality, and substantial disruption to global health systems and economies. Influenza and SARS-CoV2 have already caused pandemics while Nipah virus is an example of a pathogen with future pandemic potential. Nipah virus is particularly concerning due to its high mortality rate, which can reach up to 75%, and its record of causing sporadic yet severe outbreaks. Influenza, on the other hand, with seasonal outbreaks and historically devastating pandemics, consistently poses a significant threat, leading to millions of infections and hundreds of thousands of deaths annually, significantly straining healthcare systems and causing substantial economic burden.

In this complex and ever-changing landscape, vaccines emerge as crucial tools by offering pre-emptive protection against emerging infectious diseases, mitigating their impact and bolstering global resilience in the face of health crises.



The development of the MV-NiV vaccine candidate has gained pace.



FORGING TRANSNATIONAL PARTNERSHIPS TO TACKLE GLOBAL THREATS



Candice Marion
Vaccine Development Manager

What promising advancements have been made in Nipah virus vaccine research, and how close are we to achieving an effective vaccine for widespread use?

Nipah virus has caused severe, yet localised outbreaks in Southeast Asia in recent years and its classification as a priority pathogen by the World Health Organization has increased attention on its research agenda.

While a few Nipah virus vaccine candidates have reached early clinical stage, achieving an effective vaccine for widespread use still requires further clinical trials to confirm safety and efficacy in humans. Collaborations among researchers, governments, and healthcare organisations are critical for advancing these efforts and accelerating progress towards a vaccine that can effectively prevent future Nipah virus outbreaks.

One notable advancement in vaccine research against this deadly infection is the MV-NiV vaccine candidate, developed by the University of Tokyo, which has shown promising results in preclinical studies. This vaccine, based on a measles viral vector, has demonstrated the ability to induce strong immune responses and to protect against Nipah virus infection in animal models. With funding from AMED SCARDA (Japan Agency for Medical Research and Development, Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response), the development of the MV-NiV vaccine candidate has gained pace. Production of a demonstration batch of vaccine for nonclinical studies was thus successfully completed, an important milestone towards the first-in-human clinical testing, which is planned to commence in Europe in a close collaboration between EVI and the University of Tokyo.

Collaborations among researchers, governments, and healthcare organisations are critical for advancing these efforts and accelerating progress towards a vaccine that can effectively prevent future Nipah virus outbreaks.



William Martin
Project Manager

In light of the lessons learned from the COVID-19 pandemic, what key strategies should guide future preparedness and response to infectious diseases?


The COVID pandemic underscored the necessity of a coordinated global response to infectious threats, including an integrated European effort to prepare for future pandemics. Sharing data, resources, and expertise across countries proved to be a key determinant for effective containment and mitigation of the COVID pandemic. Collaborative efforts will continue to play an important role in the European pandemic preparedness strategy at both the preclinical and clinical levels.

At the preclinical stage we are partnering with organisations across Europe to build ISIDORe, a comprehensive research infrastructure supporting researchers and SMEs in developing new tools, including vaccines, to combat both current and future pandemic threats swiftly and effectively. For clinical trials, Europe also needs in-place infrastructure to allow rapid testing of vaccines. EVI is working with partners across Europe in the VACCCELERATE consortium, a pan-European network that serves as a single entry-point for all stakeholders for phase II and III trials of vaccines against COVID-19 and other pandemic threats. The successes of these projects demonstrate the power of coordinated, sustained international partnerships to prepare for public health emergencies.



“
**Collaborative efforts
will continue to
play an important
role in the
European pandemic
preparedness strategy
at both the preclinical
and clinical levels.**
”

Cross-cutting and implementation



The evolving landscape of vaccine research and development (R&D) underscores the critical importance of integrating transversal aspects to advance global health solutions. Innovations in vaccinology, such as artificial intelligence, organ-on-chips and human challenge models, are revolutionising how vaccines are selected, designed and tailored to combat infectious threats. In parallel, exploration into new administration routes, including mucosal delivery systems, aims to enhance vaccine efficacy and accessibility.

Combating antimicrobial resistance (AMR) using innovative vaccine strategies is another rapidly evolving frontier in vaccinology. AMR is one of the greatest global challenges of our time, rendering numerous current treatments ineffective against bacterial infections, due to the misuse and overuse of antibiotics, compounded by a decline in the development of new antibiotics driven by limited profit potential. It is estimated that 4.95 million people have died in 2019 due to AMR. Vaccines offer a proactive approach in mitigating the rise of resistant pathogens by preventing infections, reducing the need for antibiotics and averting potential health crises.

Embracing these cross-cutting aspects not only streamlines vaccine development but also holds promise in strengthening our defences against evolving health challenges, safeguarding global public health now and in the future.

BEYOND SINGLE VACCINES, PIONEERING THE FUTURE OF VACCINE R&D FOR GLOBAL IMPACT



Irina Meln
Senior Innovation Manager

What role do controlled human infection models (CHIMs) play in vaccine development, what are the main challenges they present, and how might they influence future advancements in vaccine research and public health outcomes?

CHIMs provide a controlled environment to study immune responses and assess vaccine efficacy quickly and cost-effectively. They allow researchers to rapidly determine if a vaccine candidate is potentially effective before embarking in costly and lengthy phase II clinical trials. In addition, they can help identify relevant correlates of protection (CoP) and specify endpoints for phase III trials, which accelerates decision-making, enabling resources to be focused on the most promising candidates.

However, CHIMs also present significant challenges. Ethical considerations surrounding the deliberate infection of volunteers must be carefully managed to ensure participant safety and adherence to rigorous ethical standards. In addition, third-party risks need to be considered when studies are conducted in outpatient settings. An open dialog is essential to obtain alignment between all stakeholders, including regulatory authorities, ethics committees, volunteers and patient-representing organisations.

In 2023, the Inno4Vac project held several stakeholder meetings focused on the regulatory and ethical aspects of CHIMs. EVI co-organised a CHIM meeting, held on May 22-23, 2023, in Kenya, which focused on CHIM studies conducted in endemic countries. This meeting discussed the expansion of CHIM studies in Africa, the variety of chal-

lenge organisms used, and emphasised the importance of community engagement and ethical oversight.

An ethics workshop held in May 2023 in Europe brought together experts to discuss best practices and ethical guidelines for CHIMs. The workshop aimed to ensure that CHIM studies are conducted with the highest ethical standards, focusing on the welfare of participants and the importance of community involvement in the study process.

Looking ahead, CHIMs have the potential to revolutionise vaccine research by facilitating the testing of new vaccine concepts and formulations in a controlled, efficient manner, leading to faster and more targeted approaches to public health challenges.

How can vaccines contribute to the fight against antimicrobial resistance, and what major technological advancements are enhancing their effectiveness in this battle?

AMR constitutes a major health problem in Europe and the world. Vaccines can help combat AMR by preventing infections caused by bacteria, viruses, and other pathogens, thereby reducing the need for antibiotics and limiting the emergence and spread of resistant strains. This proactive approach preserves the effectiveness of existing antibiotics and helps curb the spread of resistant strains, supporting overall public health efforts. At EVI we are pioneering mathematical modelling to demonstrate health and economic value of vaccines in combating AMR. In 2023 the PRIMAVeRa project completed four systematic reviews, of which three have

been published. PriMAVeRa advanced its theoretical model framework, selected three case studies, and engaged with over 100 database owners for data collection.

In addition, EVI is tackling AMR through advanced genomic and AI technologies and secured funding for a new project DRAIGON (start in January 2024). DRAIGON seeks to de-

velop a novel diagnostic tool that integrates whole-genome sequencing with AI to quickly and accurately identify multi-drug resistant pathogens in patients. By focusing on blood and joint infections, the project aims to improve early detection, prevent cross-border pathogen spread, and enhance global AMR surveillance.



Monika Slezak
Project Manager Consultant

What specific advantages do novel delivery methods like nasal vaccines offer over traditional injection-based approaches?

Nasal vaccines offer several advantages over more common approaches. Firstly, they can increase vaccine uptake, especially among populations such as children, who may be averse to receiving injectable vaccines.

Outstandingly, nasal vaccines can induce a protective mucosal immune response in the nasal cavity, which is the initial site of entry for respiratory pathogens. Mucosal immunity

has the potential to not only prevent disease but also inhibit infection and transmission. This dual benefit is significant, as highlighted during the COVID-19 pandemic, where vaccines primarily aimed at preventing disease have shown varying effectiveness against infection and transmission. Therefore, leveraging nasal delivery methods in vaccine development holds promise for enhancing overall vaccine efficacy in combating infectious diseases as well as uptake among the target populations. EVI is leading efforts towards development of new antigens for pathogens *Streptococcus pneumoniae* and *Bordetella sp.* together with analytical methods and model mRNA constructs for these antigens.

Capacity building and advocacy



Building collective strength for pioneering vaccine solutions

EVI is dedicated to strengthening clinical and vaccine research capacities in the fight against diseases of poverty and emerging infectious diseases, in Europe and particularly in low- and middle-income countries (LMICs).

EVI supports capacity building through activities such as fellowships, short-term courses, networking, workshops, and stakeholder meetings, and has served for almost a decade as hosting institution for the EDCTP Clinical Research and Development Fellowship Scheme and the WHO/TDR Special Programme on Tropical Diseases Research.

Short courses

As part of its capacity building activities, EVI provides a number of customised short-term courses and trainings in vaccinology and related topics. In 2023, EVI added training in vaccinology to its portfolio of short-term courses.

On May 29-31 2023, EVI Clinical Team in collaboration with Uganda Virus Research Institute-International AIDS Vaccine Initiative (UVRI-IAVI) organised a joint 3-day vaccinology course in Entebbe, Uganda. The course, supported by the Special Programme for Research and Training in Tropical Diseases (TDR) and the European & Developing Countries Clinical Trials Partnership (EDCTP), aimed at strengthening local capacity in vaccinology while also building links between vaccine researchers in Africa and Europe.

The training combined lectures with interactive sections, group discussions, and Q&A sessions on a broad range of vaccinology topics such as types of vaccines and public health benefits, basic immunology, adjuvants, vaccine manufacture, correlates of protection, preclinical and clinical vaccine development, CHIMs, clinical trial design, vaccine hesitancy, and resource mobilisation.



For more information about EVI courses and services please visit www.euvaccine.eu/services.

Master and doctoral fellowships

As part of the EDCTP2-supported Multi-Stage Malaria Vaccine Consortium (MMVC), EVI has provided Masters and PhD fellowships to a handful of talented African scientists wishing to pursue a career in malaria research and vaccinology:



Caroline Bundi
MMVC PhD fellow at
Ifakara Health Institute
Clinical Trial Facility,
Bagamoyo Research and
Training Centre, Tanzania.
Sep 2019 to May 2024

Vaccine dosing and vaccination schedule are key in determining immunogenicity, longevity, and vaccine efficacy. *P. falciparum* reticulocyte-binding protein homolog 5 (PfPRH5) and R21 are malaria vaccine candidates targeting the blood-stage and sporozoite-stage, respectively, that have been tested in malaria-endemic countries. Using samples from two clinical trials conducted using these vaccines in Tanzania and Kenya, I aim to evaluate how the following four factors affect the vaccine response. A) Previous malaria exposure (high malaria intensity versus low malaria intensity), B) Age (compare adults, children, and infants) C) Vaccine dose (different combinations of the vaccine and adjuvant dose) D) Vaccine regime (a monthly dose versus a last dose delayed to 6 months). I will model how these factors interact with each other with the aim to identify the best vaccine regime.



Elizabeth Kibwana

MMVC PhD fellow at
KEMRI-Wellcome Trust
Research programme, Kilifi,
Kenya. Oct 2019 to April 2024
My study is part of a clinical trial

to determine the efficacy of R21/MM in semi-immune adults, using the controlled human malaria infection (CHMI) model. CHMI studies involve infecting healthy volunteers with malaria parasites, monitoring parasitemia and treating them when a set threshold is reached. Malaria remains a public health concern, and the development of a malaria vaccine remains a priority. My project seeks to identify and characterise responses induced by R21/Matrix M™ malaria vaccine that may correlate with or confer protection. To do this, I carry out a variety of immunological assays to tease out vaccine-induced antibody, and cell-mediated immune responses that are associated with protection post-infection in a CHMI study. The study looks to further understand the vaccine-induced immunity, efficacy and potentially identify *in vitro* immune cell populations that correlate with protection for a novel malaria vaccine.



Prisca Yamaego

MMVC MSc fellow at IRSS-
Clinical Research Unit of Na-
noro (CRUN), Burkina Faso.
Sep 2021 to Aug 2023.

Vaccination has been shown to be one of the most effective public health interventions worldwide. Immunogenicity of vaccines administered to infants can be modulated by several factors such as age, previous exposure to malaria parasite and malnutrition. In my MSc project, I will first look at the effect of these factors on the immunogenicity of both Expanded Program on Immunisation (EPI) vaccines and the novel malaria vaccine candidate (R21/Matrix M™) in children participating in clinical trials in Nanoro, Burkina Faso. In the second analysis, I will assess whether children who respond poorly to R21/Matrix M™ vaccine also respond poorly to EPI vaccines. My findings will have public health significance by providing a better understanding on factors that modulate immune responses to vaccines intended for children in malaria-endemic settings.



Charles Mulamba

MMVC PhD fellow at Ifakara
Health Institute Clinical Trial
Facility, Bagamoyo Research
and Training Centre, Tanzania.
Sep 2019 to April 2024.

Malaria control relies heavily on the use of anti-malarial drugs and insecticides against malaria parasites and vectors, respectively. Drug and insecticide resistance threatens the effectiveness of conventional malaria interventions; alternative control approaches are therefore needed. The development of transmission-blocking vaccines that target the sexual stages in humans or mosquito vectors is among new approaches being pursued. Transmission-blocking vaccines induce antibodies that prevent malaria parasite development in the mosquito vector after a blood meal, consequently blocking onward transmission. My project sets out to evaluate the capability of a new vaccine (Pfs25-IMX313/Matrix M™) to induce transmission-blocking antibodies in individuals living in malaria-endemic areas.

Making science happen: Vaccine advocacy & research sustainability

Product Development Partnerships – Annual Meeting 2023

The Netherlands Enterprise Agency (RVO), on behalf of the Dutch Ministry of Foreign Affairs, organised the Product Development Partnerships (PDP) Annual Meeting. The event was held in Leiden and served as a platform for showcasing the Netherlands' ongoing commitment to global health through innovative partnerships.

Key representatives from the Dutch Ministry of Foreign Affairs took the stage to highlight the nation's pivotal policies and the recently unveiled Global Health Strategy for 2023-2030.

Throughout the meeting, several PDPs presented their ongoing projects, which are supported by the Dutch Product Development Partnerships Funds. The presentations shed light on the impactful work being conducted to develop products and technologies aimed at combating diseases and conditions linked to poverty and advancing sexual and reproductive health and rights (SRHR).

The Dutch government's long-standing support through the PDP scheme has been instrumental in driving advancements

in global health. By funding the development of essential health products, the Netherlands continues to play a crucial role in improving health outcomes in underprivileged communities worldwide.

The event also featured an engaging panel discussion, along with informal exchanges and networking sessions that provided valuable opportunities for interaction among partners in the field.

EU-China Vaccine Collaboration Forum 2023

The city of Wuxi hosted this event, held over two days, that was a collaborative effort organised by the EVI, the EU Project Innovation Centre (EUPIC), the Administrative Committee of Wuxi National High-New Tech Industrial Development Zone, the Wuxi Municipal Science and Technology Bureau, and the Wuxi Municipal Health Commission. It received additional support from the China Association for Vaccines, China Pharmaceutical University, and the Wuxi Municipal People's Government.

The forum attracted several hundred participants, representing a diverse mix of European and Chinese enterprises, universities, investment institutions, and industry organisations. The agenda was packed with discussions on the latest advancements in vaccine research and development, showcasing a global commitment to combating infectious diseases through cutting-edge science and technology. Central to the forum were vibrant discussions on revolution-



ary mRNA-based vaccines. These discussions delved into new methodologies and technological innovations that promise to enhance vaccine efficacy and accessibility.

In addition to the insightful presentations, the event featured matchmaking sessions designed to foster collaboration between European and Chinese researchers. These sessions facilitated in-depth discussions, allowing participants to explore potential partnerships and collaborative projects aimed at advancing vaccine research.

The 2023 EU-China Vaccine Collaboration Forum underscored the importance of international cooperation in addressing global health challenges. The organisers and participants expressed optimism that the event would pave the way for future collaborations, driving forward the development of new vaccines and enhancing global health security.

TRANSVAC, the European Vaccine Research Infrastructure: then, now and beyond

TRANSVAC is a long-standing initiative that has accelerated the development of novel vaccines by uniting institutions across Europe under a single collaborative framework. The resulting research infrastructure is now a well-known research infrastructure offering vaccine developers seamless, coordinated access to critical expertise and capabilities.

Since 2009, TRANSVAC, an EU-funded consortium, has empowered the global vaccine community by supporting the development and optimisation of new human and veterinary vaccine candidates, adjuvants, protocols, and technologies. It has provided scientific services for 88 different vaccinology projects, including 18 focused on COVID-19 during the pandemic, some of which have reached clinical testing stage. TRANSVAC continues to support the research community through its vaccine R&D service provision for epidemic-prone pathogens as part of the ISIDORE project (Integrated Services for Infectious Disease Outbreak Research).

Additionally, its highly sought-after training programme has delivered specialised vaccinology courses to over 400 professionals, covering the entire process from vaccine R&D to licensure. Looking ahead, the trainings developed within TRANSVAC2 are set to continue as an independent, sustainable training programme starting in 2024.



TRANSVAC partners at final meeting on 19-20 April 2023 in Brussels.

Corporate communications

During 2023 the EVI Communications Team has continued to expand and strengthen the organisational network and profile, both offline by assuring conference and webinar participations from colleagues and employees, and on-line by maintaining a sustainable digital community growth through social media channels as well as in the newsletter subscribers list.

Digital community

The digital community on LinkedIn grew another 45% compared to 2022 (in 2022 the growth rate was +62% versus 2021), while on Twitter the numbers showed a slower yet sustained growth of 14% compared to 2022 (2022 versus 2021 was +10%).

Newsletter

The number of newsletter subscribers grew by 14%, compared to the previous year (2022 versus 2021 growth was 33%). The Communications Team ensures that all new email addresses gathered comply with the EU general data protection regulation (GDPR).

Website development

Throughout 2023 EVI launched three new websites for the projects UliiMalVax (www.ultimalvax.eu in July 2023), NOSEVAC (www.nosevac-project.eu in October 2023), and CAPTIVATE (www.captivate-malaria.eu in February 2023), and continued reflecting updates on another seven websites for closed and currently open projects.



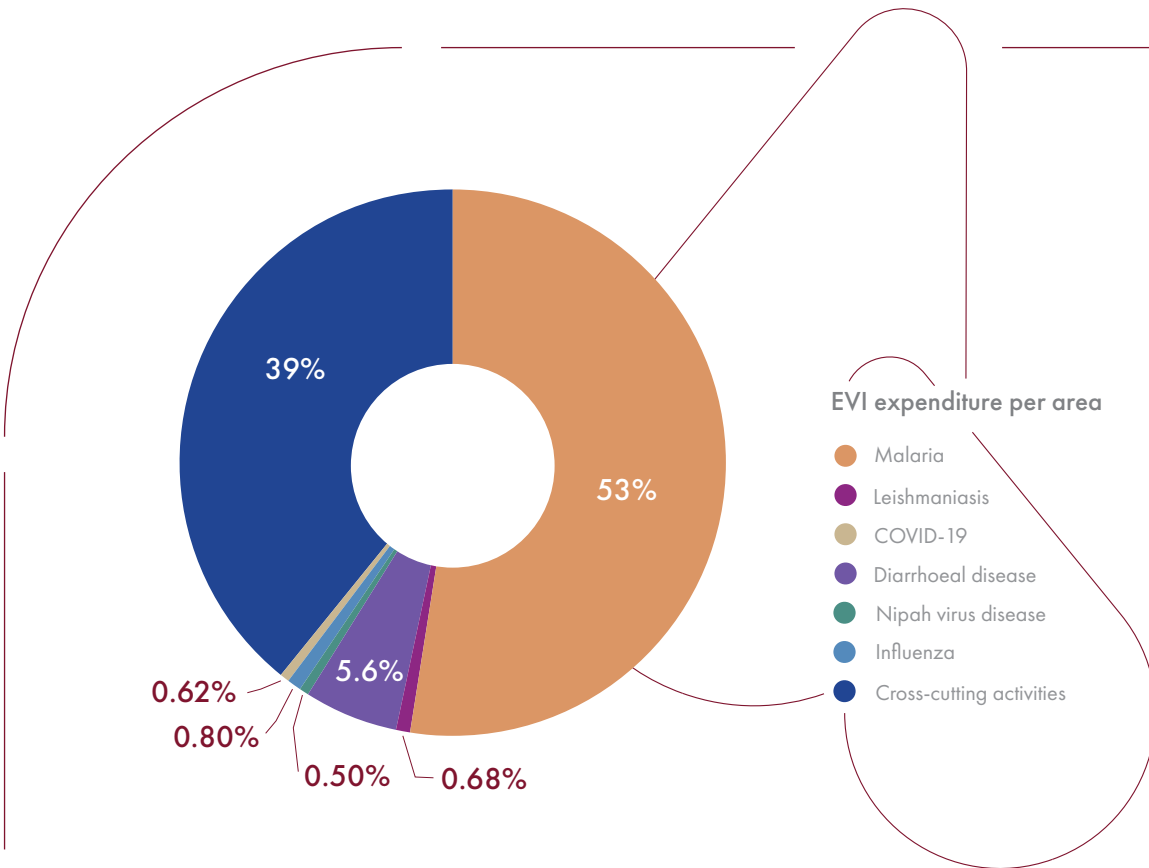
Financial performance report 2023



The year 2023 continued the financial consolidation of EVI, bringing new funding to EVI, especially for malaria activities and cross-cutting activities. The funding of EVI is therefore diversified and solid.

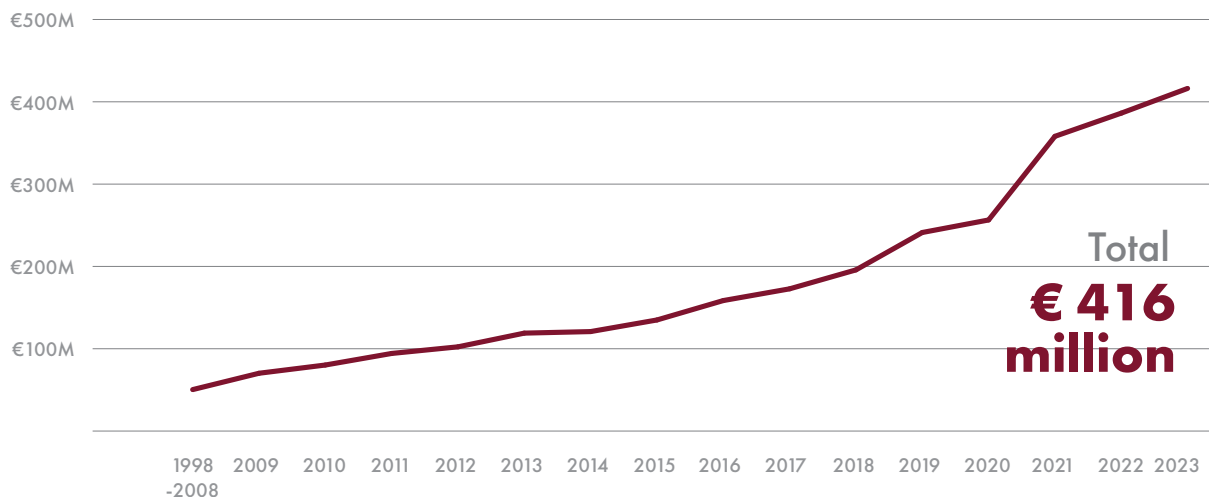
EVI came out of 2023 with a satisfactory surplus on the profit and loss with an improved solvency and therefore an increased ability to meet long-term obligations. This puts EVI in a solid financial position with adequate operating budget for pursuing the mission of EVI, including planned R&D implementation, over the next 5 years.

EVI expenditure per area



Fundraising

EVI is grateful for the continued support from its long-term funders. During the current reporting period, EVI implemented a broad portfolio of EU, EDCTP, CEPI, IMI, GHIT, DGIS and BMBF-funded activities. Since its initiation in 1998, EVI has raised almost €416 million for its mission. In 2023, approximately €30 million were mobilised for new activities.



Statement of comprehensive income for the year as of 31 December 2023

	2023 EUR	2022 EUR
Income		
Turnover from sales	121,638.04	28,000.00
Public institutional funding:		
Governmental & International Agency funding	3,253,741.49	196,896.14
European Union	11,813,752.60	9,780,534.54
European and Developing Countries Clinical Trial Partnership	1,275,725.08	2,461,096.44
Total public institutional funding	16,343,219.17	12,438,527.12
Other income net	534,226.75	274,422.73
Total income	16,999,083.96	12,740,949.85
Social mission expenditure		
Research & vaccine development expenditure:		
Malaria	8,707,022.00	3,530,886.19
Diarrhoeal diseases	931,979.76	1,512,107.95
Leishmaniasis	112,642.79	823,016.63
Nipah virus disease	82,941.59	119,759.00
Influenza	132,538.25	40,069.54
COVID-19	102,179.74	100,515.30
Cross-cutting activities	6,454,429.68	6,618,874.56
Advocacy & communications expenses	6,119.88	2,599.92
Total social mission expenditure	16,529,853.69	12,747,829.09
Supportive social mission expenditure		
Training, quality assurance and project development	-	796.54
Fundraising	5,141.81	403.61
Governance	5,946.84	4,824.80
Total supportive social mission expenditure	11,088.65	6,024.95
Non-social mission expenditure		
General executive administration	351,100.44	196,121.74
Overhead income	(419,447.13)	(237,581.02)
Total non-social mission expenditure	(68,346.69)	(41,459.28)
Total expenditure	16,472,595.65	12,712,394.76
Operating surplus / (deficit)	526,488.31	28,555.09

Statement of financial position as of 31 December 2023

	2023 EUR	2022 EUR
Current assets		
Cash and cash equivalents:		
Cash and banks - key accounts	10,989,132.39	10,251,450.03
Total cash and cash equivalents	10,989,132.39	10,251,450.03
Current accounts and receivables:		
Other receivables	20,776.21	986.45
Financial and debtor receivables	70,127.93	1,081.52
Total current accounts and receivables	90,904.14	2,067.97
Total current assets	11,080,036.53	10,253,518.00
Non-current assets		
Tangible fixed assets, net	2,753.00	6,231.00
Long term securities	4,277,736.40	1,000,000.00
Deferred Expenses	231,225.11	65,436.34
Total non-current assets	4,511,714.51	1,071,667.34
Total assets	15,591,751.04	11,325,185.34
Current liabilities		
Creditors	694,043.30	1,844,091.85
Accrued expenses	490,337.09	242,293.63
Other liabilities	160,836.95	45,348.78
Deferred income	11,647,005.58	7,120,411.27
Total current liabilities	12,992,222.92	9,252,145.53
Equity of organisation		
Operating result	526,488.31	28,555.09
Operating funds	2,073,039.81	2,044,484.72
Total equity of the organisation	2,599,528.12	2,073,039.81
Total equity and liabilities	15,591,751.04	11,325,185.34

For more detailed information about EVI's financial statements and related indicators the "2023 EVI Financial and Performance Report" is available upon request (www.euvaccine.eu/contact-us).

Governance

AS OF 31 DECEMBER 2023

The General Assembly continues to be advised on financial and legal matters by the EVI Finance and Risk Management Committee (FRMC). During 2023 the governance process was re-optimised and steps were taken to strengthen the governance of EVI. During 2023 a new representative in the General Assembly was welcomed from Institute Pasteur – Professor James Di Santo.

Publications 2023

Tiono, Alfred B et al. "Plasmodium falciparum infection coinciding with the malaria vaccine candidate BK-SE36 administration interferes with the immune responses in Burkinabe children." *Frontiers in immunology* vol. 14 1119820. 10 Mar. 2023, doi:10.3389/fimmu.2023.1119820

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Kenny, Grace et al. "Distinct receptor binding domain IgG thresholds predict protective host immunity across SARS-CoV-2 variants and time." *Nature communications* vol. 14,1 7015. 2 Nov. 2023, doi:10.1038/s41467-023-42717-1

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- Coalition for Epidemic Preparedness Innovations (CEPI), Norway
- Danida, Denmark's development cooperation, Denmark
- Danish National Advanced Technology Foundation, Denmark
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- Zoetis Belgium SA (Zoetis), Belgium

Partners

We thank all our collaborators that support our common goal of developing vaccines that create health and equity for all people.

2-control ApS	Denmark
AdaptVac APS (AdaptVac)	Denmark
African Research Collaboration for Health Limited Kenya	Kenya
Ares Genetics GmbH	Austria
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Association Internationale de Standardisation Biologique pour l'Europe	France
Batavia Biosciences B.V.	The Netherlands
BIOASTER - Fondation de Coopération Scientifique	France
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Biomedical Research Center of the Slovak Academy of Sciences	Slovakia
Camtech Innovations Limited	United Kingdom
Centre de Recherches Médicales de Lambaréné (CERMEL)	Gabon
Centre for Infectious Disease Research in Zambia (CIDRZ)	Zambia
Centre National de Recherche Scientifique et Technologique (CNRST)	Burkina Faso
Centre National Hospitalier de Pneumo - Phtisiologie	Benin
Centro Hospitalar Universitário do Porto	Portugal
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European Clinical Research Infrastructure Network (ECRIN)	CZ, FR, DE, HU, IE, IT, NO, PL, PT, SK, ES, CH

European Infrastructure For Translational Medicine (EATRIS)	BG, HR, CZ, FI, FR, IT, LV, LU, NL, NO, PT, SI, ES, SE
European Infrastructure Of Open Screening Platforms For Chemical Biology European Research Infrastructure Consortium (EU-OPENSREEN ERIC)	CZ, DK, FI, DE, LV, NO, PL, PT, ES, SE
European life-science infrastructure for biological information (ELIXIR)	GB, SE, CH, CZ, EE, NO, NL, DK, IL, PT, FI, FR, BE, IT, SI, LU, DE, HU, ES, GR, EMBL
European Marine Biological Resource Centre European Research Infrastructure Consortium (EMBRC)	BE, FR, GR, IL, IT, NO, SE, PT, ES, GB
European Research Infrastructure On Highly Pathogenic Agents (ERINHA-ERIC)	FR, HU, SE, IT, PT, NL, BE, AT, ES, GB
European University Cyprus	Cyprus
European Virus Archive – Global (EVAg)	FR, US, BE, DE, IT, UK, SN, SI, SK, CH, NL, SE, ZA, CN, SG, GR, AU, HT, HU, JO, JP, ML, KH, DZ, MG
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Forschungszentrum Jülich GmbH	Germany
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Fraunhofer Institute for Molecular Biology and Applied Ecology IME	Germany
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GlaxoSmithKline Biologicals SA	Belgium
Global Malaria Vaccines GmbH	Germany
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Hacettepe University	Turkey
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Helmholtz Centre for Infection Research (HZI)	Germany
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Institut de Recerca i Tecnologia Agroalimentàries (IRTA)	Spain
Institut de Recherche en Science de la Santé (IRSS)	Burkina Faso
Institut de Recherche pour le Développement (IRD)	France

Institut National de la Recherche Agronomique (INRA)	France
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Institut Pasteur	France
Institut Pasteur de Dakar	Senegal
Institut Pasteur de Lille	France
Institute des Sciences et Techniques (INSTech)	Burkina Faso
Institute of Endemic Diseases (IEND), University of Khartoum	Sudan
Institute of Health Carlos III	Spain
Institute of Human Virology	Nigeria
Institute of Research in Health Sciences (IRSS-DRO), Bobo-Dioulasso	Burkina Faso
Institute of Research in Health Sciences, Clinical Research Unit of Nanoro (IRSS-URCN)	Burkina Faso
Instituto de Biologia Experimental e Tecnológica (iBET)	Portugal
Instituto de Engenharia de Sistemas e Computadores, Tecnologia e Ciencia	Portugal
Instruct-ERIC	BE, CZ, EMBL, FI, FR, DE, GR, IL, IT, LV, LT, NL, PT, SL, SK, ES, UK
International Centre for Diarrhoeal Disease Research, icddr,b	Bangladesh
Intravacc	The Netherlands
Isala Hospital	The Netherlands
Israel Ministry of Health	Israel
Istituto Superiore di Sanità (ISS)	Italy
Janssen Vaccines & Prevention B.V.	The Netherlands
Johns Hopkins University	USA
Jos University Teaching Hospital	Nigeria
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Kintampo Health Research Centre (KHRC)	Ghana
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University Hospital Cologne	Germany
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Project index

Project	Funder	Project Title	Timeline
MMVC	EDCTP	The Multi-Stage Malaria Vaccine Consortium (MMVC)	01 April 2018 – 31 March 2025
MIMVaC-Africa	EDCTP	A multilateral initiative to foster the clinical development of effective malaria vaccine candidates in Africa (MIMVaC-Africa)	01 February 2020 – 31 January 2025
MVPE-CC	EDCTP	The Malaria Vaccine Pilot Evaluation-Case Control (MVPE-CC) Project	01 April 2021 – 31 December 2024
VAC4PM	GHIT Fund	Clinical development of placental malaria vaccine candidates	25 October 2021 – 30 September 2025
ADVANCE-VAC4PM	European Union	Advancing the clinical development of placental malaria vaccines in the context of capacity building and use of digital health technologies	01 June 2022 – 31 May 2027
Bmbf ADMALVAC	BMBF-kfw	Advancing next-generation malaria vaccines (ADMALVAC)	1 July 2023 – 30 June 2028
DGIS-PM	RVO PDP IV	Advancing the clinical development of placental malaria vaccines.	1 December 2022 - 1 December 2027
UliMalVax	European Union (Horizon Europe Programme)	A Vaccine Targeting Eradication of Malaria	1 May 2023 – 30 April 2027
PfRipr5-PD	GHIT Fund	Towards the clinical development of the new asexual blood-stage malaria vaccine candidate PfRipr5 (PfRipr5-PD)	29 August 2023 – 30 September 2025
CAPTIVATE	European Union (Horizon Europe Programme)	Correlates of Protective immunity-driven Investigation of malaria Vaccine combination strategies	1 November 2023 – 30 April 2028
PREV-PKDL	EDCTP2, co-funded by Wellcome Trust	Clinical development of a therapeutic vaccine for prevention of post-kala azar dermal leishmaniasis	01 April 2018 – 31 December 2025
SHIGETECVAX	European Union (Horizon 2020 Programme)	Early clinical development of a live, attenuated combination vaccine against <i>Shigella</i> and ETEC diarrhoea	01 September 2019 – 28 February 2025
ShigaPlexIM	EDCTP2	Early clinical development of an injectable <i>Shigella</i> vaccine through phase I and descending age studies with and without an adjuvant in Africa	01 October 2019 – 31 December 2025

Project	Funder	Project Title	Timeline
VACCELERATE	European Union (Horizon 2020 Programme)	European Corona Vaccine Trial Accelerator Platform	28 January 2021 - 27 January 2024
CEPI-NIPAH	Coalition for Epidemic Preparedness Innovations (CEPI)	Development of a Nipah measles vector vaccine (MV-NiV) to be used in outbreaks situation in chil- dren and adults exposed population	01 March 2019 – 31 March 2023
SCARDA-Nipah	SCARDA	Development of a Nipah measles vector vaccine (MV-NiV) to be used in outbreak situations	01 March 2023 – 01 March 2025.
CEPI- Betacoronaviruses	Coalition for Epidemic Preparedness Innovations (CEPI)	Preclinical proof of concept for broadly protective mRNA vaccine against betacoronaviruses	01 April 2022 – 31 March 2024
TRANSVAC2	European Union (Horizon 2020 Programme)	European Vaccine Research and Development Infra- structure	01 May 2017 – 30 April 2023
TRANSVAC-DS	European Union (Horizon 2020 Programme)	Design study for a European vaccine infrastructure	01 June 2020 – 28 February 2023
ISIDORe	European Union (Horizon Europe Programme)	Integrated Services for Infectious Diseases Outbreak Research	01 February 2022 – 31 December 2024
WANETAM 3	EDCTP	West African Network for TB, AIDS and Malaria	01 August 2021 – 31 July 2024
PrIMAVeRa	Innovative Medicines Initiative (IMI) and European Federation of Pharma- ceutical Industries and Associations (EFPIA)	Predicting the Impact of Monoclonal Antibodies & Vaccines on Antimicrobial Resistance	01 November 2021 – 31 October 2026
Inno4Vac	Innovative Medicines Initiative (IMI) and European Federation of Pharmaceutical Industries and Associations (EFPIA)	Innovations to accelerate vaccine development and manufacture	01 September 2021 – 28 February 2027
DRAIGON	European Union (Horizon Europe Programme)	Diagnosing Infections with Multi-Drug Resistant Micro- organisms using AI-powered Genomic Antibiotic Sus- ceptibility Prediction from Long-Read Sequencing Data	1 January 2024 – 31 December 2027
NOSEVAC	European Union (Horizon Europe Programme)	Innovative nasal vaccines to prevent pathogen colo- nization and infection in the upper respiratory tract	1 May 2023 – 30 April 2028

Report resources

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Malaria

Key Figures:

*Data refers to 2022: <https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2023>

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Diarrhoeal diseases

Key Figures:

Diarrhoeal disease fact sheet from GAVI (Diarrhoeal disease) November 2023: <https://www.gavi.org/vaccineswork/vaccine-profiles-shigella>

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Pandemic Threats

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Cross Cutting

Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *Lancet*, 399, 629-55 (2022). DOI: [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)

Capacity building

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