Malaria community efforts have saved over 10 million lives
Over the past two decades, the malaria community has saved an estimated 10.6 million lives and prevented around 1.7 billion cases.¹ MMV is proud to have contributed to this achievement: since 1999, in collaboration with partners, it has brought forward 14 medicines (see portfolio on p. 5) estimated to have saved 3 million lives.

Malaria takes the life of a child every minute
Despite this considerable progress, a child still dies from malaria every minute of every day.¹ Like other diseases, malaria thrives where access to basic health services is limited. The highest burden is borne by the African continent, where around 95% of all cases occur.¹

South America, Southeast Asia and African countries mainly in the Horn of Africa are most affected by a complex, persistent form of malaria (relapsing *Plasmodium vivax*). Patients can suffer a relapse without warning, with debilitating symptoms and loss of economic opportunity (repeated absences from school and work).

Poverty is both a cause and consequence of malaria, a treatable and preventable disease that affects around 240 million people globally.² Children and pregnant women are its most frequent victims.

MMV works with local partners to bring forward life-saving tools
Life-saving tools that provide a path to wellbeing should be tailored to the health needs of the populations they serve. This is why—from laboratory to patient—MMV works with local partners to discover, develop and deliver critically needed medicines.

In 2022, MMV worked with partners in Africa and Europe to launch a hub for West-African drug discovery at the University of Ghana. The hub aims to build on existing expertise in medicinal chemistry and biology, and establish new drug discovery capabilities. Expertise and training is provided by longstanding MMV partners, the University of Dundee and H3D at the University of Cape Town. H3D is the first fully integrated African drug discovery hub that has worked with MMV since 2011 and has delivered two malaria drug candidates.

Delivering new drug candidates, and testing them in the field, is a crucial step in tackling the serious threat of antimalarial resistance. In 2021, MMV and Novartis, along with nine clinical trial partners (eight in Africa and one in India) successfully advanced through Phase II clinical trials a next generation therapy (ganaplacide-lumefantrine) for uncomplicated malaria in adults and children.

Tackling malaria saves lives and contributes to health and opportunity
MMV’s antimalarial portfolio, assembled with partners (see p. 5), contains compounds targeting unmet medical needs, including medicines for children, pregnant women, and people suffering from relapsing and drug resistant malaria. These medicines hold the promise of giving populations at risk of malaria a better chance to live healthy and productive lives.

It is not enough to discover and develop life-saving medicines; one must ensure that they reach patients in need. The COVID-19 pandemic revealed vulnerabilities in the supply of malaria medicines, many of which are produced far from Africa where 95% of cases occur.¹ In 2022, Universal Corporation Ltd. Kenya, became the first African manufacturer to gain WHO prequalification of a preventive malaria medicine (sulfadoxine-pyrimethamine), with support from MMV and Unitaid. This milestone strengthens manufacturing autonomy on the African continent and contributes to securing the regional supply of vital malaria medicines for two key populations—pregnant women and infants.

MMV’s business model—innovation in malaria drug development

Product Development Partnerships

- develop and facilitate access to new tools for diseases like malaria, that offer limited commercial incentive to innovate
- have delivered more than 65 new health technologies that have protected and saved the lives of more than 2.4 billion people²
- leverage the expertise and resources of a network of partners to minimize risk and maximize value
- support global health security priorities, e.g., pandemic preparedness, antimicrobial resistance and stronger local health systems²


Quality medicine at an affordable price

MMV strongly believes that all malaria patients, rich or poor, deserve treatments that are high quality, efficacious and well tolerated. In order to ensure that is the case, all new medicines supported by MMV must meet internationally accepted standards set by Stringent Regulatory Authorities (SRAs) and/or WHO prequalification.

All development projects conducted by MMV and partners follow ICH³,⁵ guidelines every step of the way—from GLP⁴ standards for preclinical work to GCP⁵ standards for clinical trials in malaria-endemic countries that also adhere to national regulations. This is underpinned by strict adherence to GMP⁶ requirements for both investigational and registered products.

When MMV and a partner enter into a contractual relationship, they jointly commit to developing a product that will be accessible and affordable for endemic populations.

To keep the development costs as low as possible, MMV benchmarks costs and follows a robust procurement process when engaging with research service providers. We also aim to contain production costs by working with our partners to seek the most efficient routes of synthesis for our medicines—beyond reductions expected from economies of scale.

In this way, MMV is able to maximize the value of every donor dollar to our highly focused mission and develop high-quality medicines that are affordable for vulnerable populations.

MMV’s Product Development Partnership (PDP) continues to bear fruit. Combining the technical skills of our network of partners from industry and academia with in-house expertise, MMV remains a highly productive and cost-effective research and development (R&D) organization.

Each partner brings technical know-how, enabling technologies, research facilities and funding. MMV brings a wealth of malaria and R&D knowledge together with industry-style portfolio management. Our Target Product Profiles and Target Candidate Profiles (see p. 5) provide a clear framework for R&D. With this in mind, support is provided for the most promising drug candidates, while those that do not meet the target profile are quickly terminated.

This rigorous candidate selection and management enables us to maximize value while accelerating the progress of compounds through the pipeline.

A network of over 400 dedicated partners

232 years of in-house malaria experience

Direct and in-kind support from our public and private partners more than triples the value of each donor dollar for R&D.

Goal:

50 cents or less to treat a child

³. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
⁴. Good Laboratory Practice (GLP)
⁵. Good Clinical Practice (GCP)
⁶. Good Manufacturing Practice (GMP)
Almost 3 million lives saved by MMV-supported medicines

1. **NO POVERTY**
   MMV develops and facilitates access to affordable and effective therapies, key to mitigating the impact of malaria on poor populations.

2. **PARTNERSHIPS**
   Partnership is at the core of MMV. We bring together academia, pharma, research institutes, philanthropic organizations and funders to make malaria drug research happen.

3. **GOOD HEALTH AND WELL-BEING**
   MMV and partners have assembled the largest ever portfolio of antimalarials, supporting target 3.3 (to end malaria and other diseases).

4. **REDUCED INEQUALITIES**
   MMV is committed to facilitating equitable access to antimalarials for under-served populations, across all gender, age and socio-economic categories.

5. **GENDER EQUALITY**
   Malaria disproportionately affects women as patients and caregivers. MMV prioritizes new medicines specifically for use by pregnant women and girls.

6. **INDUSTRY INNOVATION AND INFRASTRUCTURE**
   MMV works with drug research and manufacturing partners in endemic countries to help strengthen local capabilities and achieve global quality standards.

7. **DECENT WORK AND ECONOMIC GROWTH**
   MMV advances the availability of antimalarials for workers and their families, contributing to decreased absenteeism at work and school, thus fostering a brighter future.

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Almost 3 million lives saved by MMV-supported medicines
Working in partnership

Over the past two decades, MMV has worked with more than 400 partners globally, including over 200 in malaria-endemic countries. These include research and implementation partners, manufacturers and local governments.

More than 200 partners

in malaria-endemic countries

The road to health impact

Developing new life-saving antimalarials is not enough to ensure patient impact. MMV believes that medicines are only effective once they are in the hands of patients who need them. Thus, we are deeply committed to building better access to our medicines. Here are some of the challenges we face, and how we work to overcome them.

Planning for access begins well before products are launched. Patient and caregiver needs inform the R&D process before drug development is finalized, enhancing product acceptability and adoption. This includes palatability testing for children and refined product packaging for ease of use and distribution. MMV also develops and provides training materials, as it is critical to ensure healthcare professionals readily understand how to administer new medicines safely and effectively and adhere to treatment schedules.

After medicines are quality-approved by Stringent Regulatory Authorities (SRAs), they are registered by national regulatory agencies in endemic countries. Registration lead-times can exceed 18-24 months in many countries (and there are over 50 malaria-endemic countries worldwide). MMV engages with regional regulatory harmonization approaches, which can help accelerate these approval processes. Before a drug becomes available, national regulators or malaria control programmes may request evidence about how new medicines work in “real-life” settings – such requirements may trigger additional research. Registration alone does not, however, translate into inclusion in national treatment guidelines. WHO’s Guidelines for Malaria provide global guidance to countries to help bolster country confidence in policy adoption of new medicines, and MMV carefully monitors evidence requirements that can support the WHO policy process and/or national adoption process.

Ensuring uptake and impact new of antimalarial medicines requires knowledge of the markets within which they will be distributed. An imperative to understand market and impact drives MMV to invest in both quantitative and qualitative market research. In addition, linking our pharma partners with market demand forecasts helps ensure advanced visibility for them to prepare for the evolving demand for their products.

International and domestic financing are also critical, as new products may be more costly than well-established multi-sourced medicines, often due to comparatively lower volumes at launch. MMV carefully considers opportunities for such financing.

Lastly, difficult lessons from COVID-19 have shown the importance of ensuring supply chains for global health products are sufficiently diversified so that low- and middle-income countries are not left vulnerable to supply disruptions of key materials. To help mitigate this risk, MMV is working closely with several African pharmaceutical manufacturers to produce antimalarials closer to where patients need them.

Today, an estimated 627,000 people still die from malaria every year. By increasing the accessibility of both existing and new antimalarials, we are working with partners in pursuit of a future where no one will suffer or die from malaria.
### Target product profiles (TPPs)

<table>
<thead>
<tr>
<th>3-day cure, artemisinin-based combination therapies (TPP1)</th>
<th>Non-artemisinin therapy for uncomplicated malaria treatments and resistance management (TPP1)</th>
<th>Intermittent preventive treatment (TPP1)</th>
<th>Severe malaria treatment/pre-referral intervention (TPP1)</th>
<th>Products targeting prevention of relapse for <em>P. vivax</em> (TPP1)</th>
<th>Chemoprophylaxis (TPP2)</th>
</tr>
</thead>
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### Target candidate profiles (TCPs)

- Asexual blood stages (TCP1)
- Relapse prevention (TCP3)
- Causal prophylaxis (TCP4)
- Transmission reduction (TCP5, 6)

- Global Fund Review Panel reviewed product – permitted for time-limited procurement, while regulatory/WHO prequalification review is ongoing
- Paediatric formulation
- WHO prequalified OR approved/positive opinion by regulatory bodies who are ICH* members/observers
- Via a bioequivalence study
- Past partners are in brackets

*International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

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**GOVERNANCE**

- **ESAC** Expert Scientific Advisory Committee
- **GSB** Global Safety Board
- **APMAC** Access & Product Management Advisory Committee
- **APM** Access & Product Management
Medicines for Malaria Venture receives sustained funding and support from government agencies, private foundations, international organizations, corporations, corporate foundations and private individuals. These funds are used to finance MMV’s portfolio of R&D projects as well as specific, targeted access and delivery interventions that aim to make it easier for populations at risk to access MMV products.

Since its foundation in 1999, MMV’s R&D portfolio of new and innovative antimalarial medicines remains the largest ever built. With partners, MMV has brought forward 14 new antimalarials. Together, these medicines have saved almost 3 million lives. Sustaining this work is critical to achieving the WHO’s Global Technical Strategy for Malaria and the UN Sustainable Development Goals (see p. 3).

**Figure 1** Diversity of funding sources

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**MMV total donation revenue 2021:** 84.1 m 100%

**Figure 2** 84% of funding directly supports R&D and Access initiatives

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- Dr Aileen Alisop, Dr David Brandling-Bennett
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