



R&D for Malaria

How new tools can transform the fight



About half of the world’s population is at risk of malaria—a life-threatening mosquito-borne disease that devastates communities and countries. In 2022, there were an estimated 249 million cases of malaria in 85 countries, claiming the lives of approximately 608,000 people—80% of whom were young children. Thanks to malaria control interventions, more than 1.5 billion malaria cases and 7.6 million deaths were successfully averted between 2000 and 2019. Yet, despite this progress, challenges like growing drug and insecticide resistance hinder control efforts. Unfortunately, 2022 saw a continued increase in new cases—indicating stalled progress and underscoring the urgent need for new solutions to complement existing interventions.

Nearly half

the world’s population is at risk

249 million

cases of malaria in 2022

608 thousand

deaths from malaria worldwide in 2022

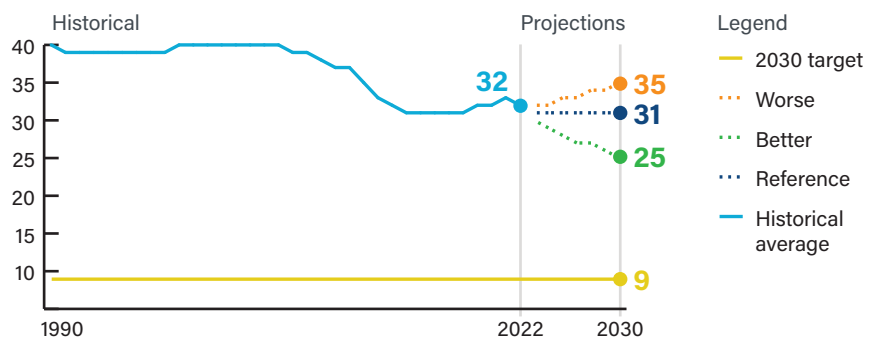
🔍 Research successes

Technologies have transformed the fight against malaria:

- **Vector control tools**, like **insecticide-treated nets (ITNs)** and **indoor residual spraying**, have driven dramatic declines in malaria. Recently, a **new generation of dual-ingredient ITNs** was introduced to respond to rising insecticide resistance.
- **Artemisinin-based combination therapies (ACTs)**, first developed in the 1990s, have become the gold standard treatment. **Child-friendly ACTs** followed, like Coartem® Dispersible, which has saved more than 1 million child lives since 2009.
- **Seasonal malaria chemoprevention (SMC)**, the use of antimalarials for prevention, was first introduced in 2012. It has saved 700,000 child lives and prevented 160 million infections.
- **Rectal artesunate and injectable artesunate**, key combined medicines addressing severe malaria, have saved more than 98,000 and 1.25 million additional child lives, respectively.
- **Two malaria vaccines** have been approved since 2021. Eight countries now offer one in their childhood immunization programs.
- Tafenoquine, a **single-dose medicine** for *Plasmodium vivax* malaria, was approved in 2018, with a pediatric version approved in 2022. A point-of-care diagnostic test to guide its use was approved in 2019.
- Since 2019, more than 1 billion **genetically modified mosquitoes** have been released globally to reduce malaria’s spread.

📈 Continued progress is possible, not inevitable

New cases of malaria per 1,000 people



📦 Key missing tools

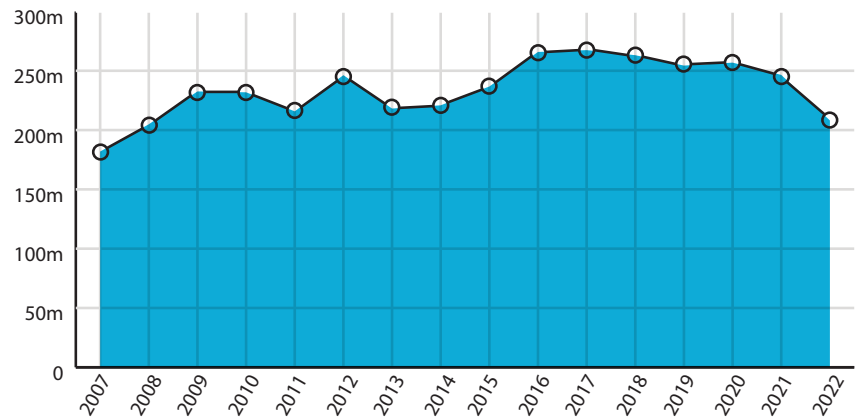
To end malaria, we need new prevention and treatment tools, including:

- **New vector control tools**, including new and longer-lasting insecticides to address resistance and biological control methods to reduce mosquito populations.
- **New treatments and approaches to stem drug resistance**, including artemisinin alternatives, novel regimens, easier-to-administer solutions like single-dose cures, and innovative delivery approaches to reduce pressure on existing treatments.
- **Novel drugs** to block transmission and prevent reinfection, **endectocides** to kill the mosquito vector, and **more antimalarials approved for children and pregnant individuals**.
- **Novel, single-dose preventative therapies** like monoclonal antibodies and long-acting injectables, which can complement other prevention tools like bednets, vaccines, and SMC.
- **Improved rapid diagnostic tests** for low-resource settings that can detect all stages and all species of malaria equally well for early, accurate diagnosis and effective surveillance.
- **Next-generation malaria vaccines** with longer duration and/or increased efficacy, including vaccines that block human-to-mosquito transmission of the parasite.

💡 Breakthroughs on the brink

- Three promising **monoclonal antibodies for malaria**, all supported by NIH, are in development, as well as several **long-acting injectable malaria prevention drugs**, including one supported by NIH, which could not only simplify and improve malaria prevention by eliminating the need for daily pills but could also reduce the emergence of drug resistance.
- More than a dozen **malaria vaccine candidates** are in late-stage clinical development, including candidates supported by NIH, DoD, and USAID.
- A novel vector control solution called **Attractive Targeted Sugar Bait**, which uses plant sugars to attract mosquitoes combined with an ingestible toxin that kills them but is safe for humans, holds promise to address the growing threat of outdoor biting by mosquitoes. The tool, which is commercially available in the United States, is undergoing validation testing for malaria control in Africa.
- A first-of-its-kind test that **diagnoses malaria using a patient's saliva**, rather than blood, is in commercial development. Developed with NIH support, the test is less invasive than other methods and delivers results quickly at the point of care.
- A **first-of-its-kind malaria treatment designed specifically for babies less than 10 pounds** has completed Phase 2/3 trials. There is no approved treatment for small babies, who are currently treated with a partial dose of medicines made for larger children, which can heighten the risk of overdose among this very vulnerable population.
- A new **malaria treatment combination**, gananplacide/lumefantrine-SDF, which consists of a novel drug and a new, optimized formulation of an existing drug, is currently in Phase 3 trials. It has the potential to clear malaria infection, including drug-resistant strains, and block transmission of the malaria parasite.
- Progress is being made toward additional **simpler dosing treatment regimens** that could require as little as one dose.

US government investment in malaria R&D (in 2022) US\$ millions



🇺🇸 US Government R&D efforts

The US government is leading efforts to advance research and development (R&D) to combat malaria through a whole-of-government approach:

- **National Institutes of Health (NIH)** conducts basic and clinical research for new treatments, vaccines, diagnostics, and vector control products.
- **Department of Defense (DoD)** undertakes research to protect US service members against malaria—the leading infectious disease threat to US service members abroad—including drug, vaccine, and vector control research.
- **US Agency for International Development (USAID)** leads the interagency President's Malaria Initiative (PMI) and supports the development of new vaccines, antimalarials, insecticides, and novel vector control tools for low-resource settings.
- **Centers for Disease Control and Prevention** jointly implements PMI, conducts surveillance and monitoring research, and develops and evaluates malaria control interventions such as bednets and other tools to improve public health efforts.
- **Food and Drug Administration** administers the Tropical Disease Priority Review Voucher Program to incentivize investment in products for neglected diseases, including malaria.

