

Staying the course?

MALARIA RESEARCH AND DEVELOPMENT
IN A TIME OF ECONOMIC UNCERTAINTY

EXECUTIVE SUMMARY



MALARIA CONTINUES TO BE AN ENORMOUS ECONOMIC AND HEALTH BURDEN on developing countries, where more than three-quarters of a million deaths occur each year, mostly among children living in Africa. However, for many decades, control efforts have been hindered by low levels of investment in research and development (R&D) of new products. Fortunately, a dramatic increase in support for R&D since the mid-1990s means funders are now well on the way to achieving global malaria control, treatment and elimination goals and, with maintained commitment, should reap the rewards in the next five to six years. However, these gains are fragile and may be reversed without continued funding and changes to funding patterns during this same time period.

Malaria R&D funding

Investment in malaria R&D has quadrupled in the past 16 years, from \$121 million in 1993 to \$612 million in 2009, with a particularly rapid increase since 2004. Funding is not spread evenly between product areas, reflecting differing costs of product development and differing levels of maturity of each portfolio, but also donor funding preferences. As a result, between 2004 and 2009, 38% of R&D funds were invested in drugs, 28% in vaccines, 23% in basic research, 4% in vector control products and 1% in diagnostics.

Malaria R&D funding by product

Between 2004 and 2009, nearly two-fifths (\$752 million, 38%) of R&D funding was invested in the drug portfolio, although with a trend of steady decline in drug funding and funding share since 2007. Although this decrease is largely due to successful completion of several antimalarials, it also appears partially linked to a general trend away from product development funding and product development partnerships (PDPs). Vaccine development accounted for just more than one quarter (\$544 million, 28%) of global R&D funding from 2004 to 2009, with a steep increase since 2007 associated with the progression of the RTS,S vaccine candidate into large-scale Phase III trials in Africa. R&D for vector control, which includes pesticides and biological control products, received only \$72 million (4%), reflecting both lower development costs and under-reporting, since no surveys have fully captured investment in this area by agrochemical firms. Expert estimates suggest these firms invested a likely additional \$20 million in the 2007–2009 period; however, exact figures are unknown. Diagnostic R&D received \$23 million (1%), reflecting both lower development costs and underfunding. While poor reporting of investment by malaria strain makes analysis difficult, only 3% of R&D funding was reported as dedicated specifically to *Plasmodium vivax*, compared to nearly 45% for *P. falciparum* (more than 50% of funding was not attributed to any strain).

Malaria R&D funders

Funding for malaria R&D is characterised by a heavy reliance on public and philanthropic funders, and a high degree of concentration. Public and philanthropic organisations provided 83% (\$1.39 billion) of malaria R&D funding between 2007 and 2009, including public investment of \$810 million (48%) and \$577 million from philanthropic groups (35%). Public and philanthropic organisations also accounted for 94% of growth in malaria R&D funding during that time. Industry's reported collective investment totalled \$281 million in 2009 (17%).

Two organisations—the Bill & Melinda Gates Foundation and the US National Institutes of Health (NIH)—provided a striking half of global malaria R&D funding in 2007–2009, and were responsible for 85% of the global increase in malaria funding. The Gates Foundation was the single largest funder, providing 30% of global funding in 2009, while the US NIH provided 19%. In the public sector, the United States dominated, providing more than half of all public investment each year, and five times more than any other government.

Malaria product developers

More than two-thirds (\$945 million) of malaria R&D activity between 2007 and 2009 was conducted by public groups (academic, government and other public institutions), while industry was responsible for just less than a third (\$468 million). Public groups accounted for virtually all basic research activity and 60% of global diagnostic R&D. Industry played a particularly dominant role in drug R&D, accounting for more than 60% of discovery and preclinical activity and just less than 40% of clinical development, while vaccine R&D was divided almost equally between public groups and pharmaceutical companies (51% and 44%, respectively). Reported data for vector control R&D suggested that public groups were responsible for three-quarters (78%) of all activity; however, when estimates of industry activity are used to supplement G-FINDER (Global Funding of Innovation for Neglected Diseases) data, public groups represented just more than half of all vector control R&D (53%), with industry responsible for a further third (34%).

PDPs played a central role, managing around one-quarter of all malaria R&D funding, nearly 40% of global grant funding and half of all drug and vaccine projects in the global malaria R&D pipeline. These PDPs relied heavily on only six donors, particularly the Gates Foundation, which provided more than three-quarters of malaria PDP funding in 2008–2009.

The malaria R&D funding gap

Overall, malaria R&D funding has been on track over the past five years to meet the global community's R&D product development goals. If this funding trend continues—with provisos—there will be no funding gap. This will require a modest 2% per year increase in malaria R&D funding each year, from \$612 million in 2009 to a maximum of \$690 million in 2015, with an investment spike of around 15% in 2016 to support late-stage products. Funders will then be able to decrease their malaria investments by about 5% per year from 2017 onward, as the fruits of their earlier investment come to registration.

The provisos: in particular, malaria R&D funding is not efficiently distributed and this urgently needs to be improved. Drug funding must remain at current levels until 2016 (and must stop its current decline), at which point it can begin winding back. (We note, though, that more accelerated drug delivery could be achieved with higher funding in the short- to mid-term.) Vaccine funding needs to remain at or slightly less than current levels until 2016–2017 but will then need a major boost as next-generation vaccines move into advanced development. However, diagnostic funding needs to quadruple immediately to around \$50 million per year in order to meet initial demand, while vector control funding needs to increase from its base of \$28 million/\$35 million in 2009ⁱ to a peak of around \$90 million per year in 2016–2017 to make new products and paradigms available. These investment injections could be funded from the annual increases projected above.

ⁱ The lower figures are reported investment; the higher figure includes estimated unreported industry investment.

Discussion

This analysis shows that malaria R&D does not need an endless blank cheque but rather requires realistic and feasible levels of funding, and has clearly defined goals and exit points as each desired product is brought to registration. It is also clear that maximum savings in lives and dollars will be achieved by adequate up-front funding, rather than provision of inadequate funds over many years.

However, much of this investment will be wasted without improved R&D funding policies. In particular, better distribution of funding between product areas; more responsive and flexible funding, particularly in the public sector; and far greater coordination of R&D funding between all sectors—public, private and philanthropic. Other areas of concern are the dependence on a very small number of funders, which has implications for funding security, and the plateau of funding for PDPs, which may reflect the impact of the global economic crisis, and is of concern given PDPs' central role in developing the global malaria portfolio.

Conclusions and recommendations

Recent marked increases in malaria R&D funding have moved endemic countries closer to the drugs, vaccines, diagnostics and vector control products needed to control and progressively eliminate and eradicate malaria. Success is very close; however, it cannot be achieved without important changes to funding and funding patterns, as listed below:

1. Malaria R&D funding needs to increase modestly for the next five to six years (2% per year until 2015, 15% in 2016) and can then begin to decrease.
2. Funding must be better distributed between product areas. A high percentage of the proposed funding *increase* should be used to support the severely underfunded diagnostic and vector control areas, and greater funds need to be dedicated to *P. vivax* product development.
3. R&D funding, particularly in the public sector, must be more flexible and responsive to global portfolio developments and goals.
4. Funders must be given improved information and tools to allow them to better coordinate funding and portfolio decisions; this includes the public, philanthropic and private sectors.
5. More funders need to become engaged in malaria R&D, including more economically advanced countries (G8/G20/Organisation for Economic Co-operation and Development), and research and science and technology agencies in both existing and new donor countries.
6. PDP funding should be maintained, since PDPs account for nearly half of the current product pipeline and virtually all new malaria products delivered in the past five years.

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