POLICY CURES RESEARCH.

Malaria R&D Funding Needs: 2021-2030

An Updated Cost Estimate for the Global Technical Strategy

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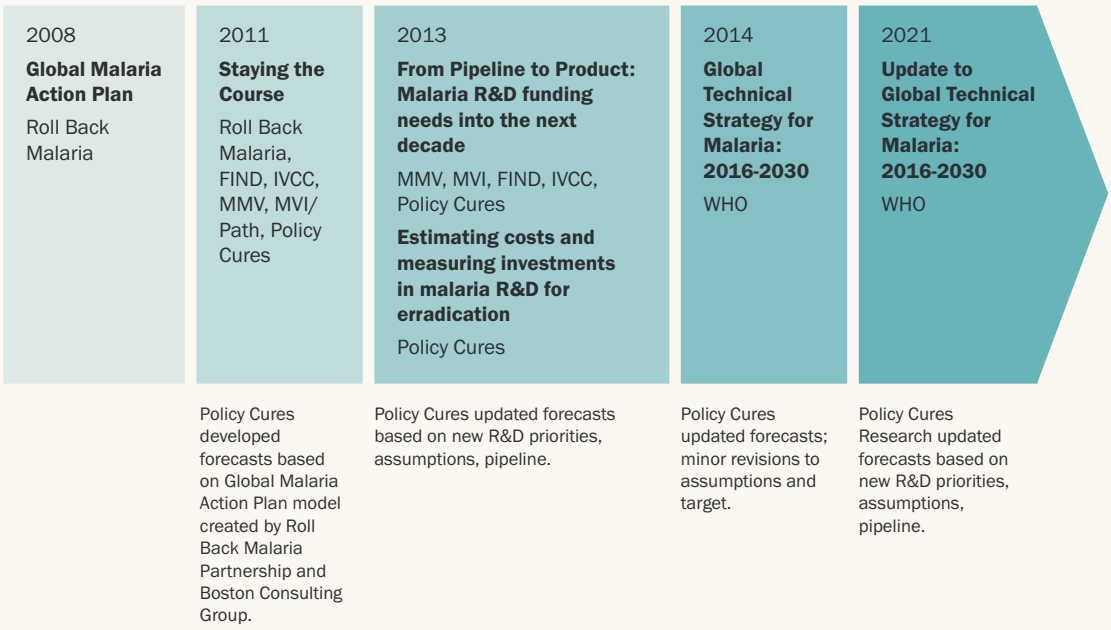
Background

In 2020, the WHO Global Malaria Programme (GMP) initiated a review and update of the Global Technical Strategy for Malaria: 2016-2030 (GTS). As part of this effort, GMP commissioned Policy Cures Research (PCR) to undertake a cost modelling exercise to review and update the malaria research and development (R&D) funding estimates that were included in the original GTS.

The original modelling work to cost the R&D elements of the GTS was completed in late 2014 by Policy Cures (the predecessor organisation to PCR) and was based on updated and adapted assumptions from modelling undertaken for two concurrently developed reports released in 2013: *From Pipeline to Product: Malaria R&D Funding Needs and Estimating Costs and Measuring Investments in Malaria R&D for Eradication*. That work in turn built on the 2011 Staying the Course report and the 2008 Global Malaria Action Plan.



This update is not intended to be a wholesale revision of the original modelling exercise, but instead to provide a refreshed estimate of the R&D funding needs for the remaining years of the GTS period, that takes into account changes in the malaria R&D landscape in the years following the original modelling exercise, including new or evolving research priorities; improved assumptions; and progression of the R&D pipeline. It compares the updated figures with the original estimates, outlining the major drivers for any changes, and describes how well actual historical global R&D investment has aligned with the original projections.

This paper details PCR's research methodology, the structure and functionality of the cost model, and a review of the overall and product-specific findings covering the estimated funding needs to advance the R&D priorities for malaria drugs, vaccines, diagnostics, biologics, endectocides, vector control products (VCP), and basic research.

Methodology

Structure of the model

The model used for this costing exercise was built on the model used in previous reports. It captures the estimated funding needs to advance malaria R&D targets and priorities for drugs, vaccines, diagnostics, biologics, endectocides, vector control products, and basic research. The goal of the cost update effort was to utilise, as a foundation, the original cost model (acknowledging and navigating its existing constraints) and to:

adjust, where practicable, the product-specific targets and assumptions to reflect the latest consensus on the malaria R&D roadmap for 2030

update the model with the current active pipeline of malaria products; and

provide a refreshed estimate of the annualised R&D funding needed to advance existing and new candidates through the pipeline to achieve the stated targets by 2030.

The model has three approaches for calculating the estimated cost of R&D. The most sophisticated approach is to map each currently active product candidate in the R&D pipeline to the identified R&D targets, and calculate the cost needed to reach those targets given the state of the pipeline, and product-specific assumptions for the cost, duration and likelihood of success for each of the stages of the product development process (e.g. per clinical trial phase). This is the approach we used for vaccines, drugs, biologics and endectocides. A second approach was used for vector control products (VCPs) and diagnostics; this approach primarily relied on activity-based cost assumptions for each of the agreed targets, largely due to either the absence or the inapplicability of validated stage-specific estimates for cost, duration or attrition. This was the same approach taken for these two product areas on the previous modelling effort. In this approach, existing product candidates are not explicitly included in the calculation, however the current state of research has been considered in the setting of the targets and costing the various agreed activities. The simplest approach used was to assume a constant cost per year, based on actual historical funding data for that area. This is the approach we used for basic research, necessitated by the diversity and breadth of activities in this category.

Key variables and inputs used in the model

- All malaria drug, vaccine, endectocide and biologics (i.e. mAbs) candidates in the pipeline (as of November 2020), including their current stage of development
- Clinical trial status for vaccines (completed or active)
- Malaria R&D portfolio targets (type and number of products needed) for drugs, vaccines, diagnostics, biologics, endectocides and vector control products
- Phase duration for each phase of each product type

Key variables and inputs used in the model

- Cost per phase (excluding cost of failure) for each phase of each product type
- Probability of technical success (defined as percentage of candidates successfully reaching the next phase) for each phase of each product type
- Ongoing annual cost estimates for basic research
- Sunk cost assumption (defined as an average of how much of a candidate's phase cost has already been incurred)
- Value adjustment (cost of capital, uncertainty multiplier)

Review and update of product targets and assumptions

The PCR team reviewed three key publications to identify the current consensus on global malaria R&D priorities as the basis for adjusting the 2030 R&D targets used to drive the model.

Key publications

- WHO Global Malaria Programme. 'Analysis of Research and Development Priorities for Malaria – Working Paper'. World Health Organisation, 2018.
- Rabinovich RN, Drakeley C, Djimde AA, Hall BF, Hay SI, Hemingway J, et al. 'MalERA: An Updated Research Agenda for Malaria Elimination and Eradication'. PLOS Medicine 14, no. 11 (30 November 2017): e1002456. https://doi.org/10.1371/journal.pmed.1002456.
- WHO Strategic Advisory Group on Malaria Eradication. 'Malaria eradication: benefits, future scenarios and feasibility. A report of the Strategic Advisory Group on Malaria Eradication.' Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO

PCR also reviewed the model's assumptions (phase duration, cost, and probability of technical success) by benchmarking them against other relevant R&D cost modelling tools/data sources:

- Terry, Robert & Yamey, Gavin & Miyazaki-Krause, Ryoko & Gunn, Alexander & Reeder, John. (2018). 'Funding global health product R&D: The Portfolio-To-Impact Model (P2I), a new tool for modelling the impact of different research portfolios'. Gates Open Research. 2. 24. 10.12688/gatesopenres.12816.2.
- Centre for Medicines Research (CMR) and Pharmaceutical Benchmarking Forum (PBF) anti-infective benchmarks, and 2009–2014 MMV realised success rates, in: Burrows, J.N., Duparc, S., Gutteridge, W.E. et al. 'New developments in anti-malarial target candidate and product profiles'. Malar J 16, 26 (2017). https://doi.org/10.1186/s12936-016-1675-x)

Additionally, PCR and WHO consulted various malaria R&D sector experts who provided, where possible, feedback and inputs on the above-mentioned product-specific categorisations, targets, and assumptions that emerged from the literature review and desk research. The list of experts that were consulted is included in *Annexe I*. Where material, these changes have been explained in the product sections below.

Curation and validation of the current malaria R&D pipeline

Policy Cures Research maintains a neglected disease R&D pipeline tracker, which includes a comprehensive list of product and technology candidates in the development pipeline for 35 neglected diseases, and covers all product categories including drugs, vaccines, diagnostics and vector control products, as well as all stages of research, from early-stage R&D through to product registration. Utilising data from this R&D tracker as a starting point, PCR undertook a thorough landscape review and validation of the current pipeline of malaria drug, vaccine, endectocide and biologic candidates as of November 2020, and used these as inputs to the model.[1]

Undertaking the modelling

The model for drugs, vaccines, biologics and endectocides used the existing pipeline and R&D targets identified in the literature review to reach the cost estimate. Each candidate in the pipeline was allocated to a relevant target. The probability of technical success (PTS)-adjusted cost was then calculated for each candidate, phase, and year, beginning from its current stage of development through to the completion of Phase IV.

If the portfolio of existing candidates was insufficient to reach a specific target (given the current stage of the candidates and the PTS for progression) the model 'backfilled' the necessary level of pipeline growth, calculating how many discovery and preclinical programmes were required to supplement the existing pipeline candidates in order to reach the target.

Where the model resulted in an unrealistic number or timing of backfill programmes (e.g. 200+ preclinical programmes for transmission-blocking *Plasmodium vivax* vaccines starting in 2021), we made adjustments to reflect a more realistic rate of pipeline growth. Each of these customisations are described in the relevant product sections below. It is worth noting that in some cases, such as for vaccines, the targets are not reached by 2030, despite the backfill.

Modelling the estimated funding needs for the target malaria diagnostics and VCPs relied on cost and duration assumptions for a variety of agreed, product-specific R&D activities (e.g. enabling science, capacity building, technology scouting, etc.). Development phase-based PTS assumptions were not factored into the modelling of these product categories.

The cost of basic research was modelled as a constant annualised figure.

We included minimum and maximum bounds for each of the phase- and activity-based cost assumptions (as well as for basic research). As a result, we have modelled both minimum and maximum funding needs scenarios for the overall malaria R&D funding need, as well as for each product type. All costs are in 2019 USD. Where cost assumptions from previous modelling efforts have been used, the figures have been inflated to 2019 USD. Finally, a cost of capital (4%) and

1 The methodology for the collection and validation of PCR's R&D pipeline tracker data is described here: https://www.pipeline.policycuresresearch.org/. Note that the candidate data in the public tracker page is updated as of August 2019, so does not reflect the November 2020 data used in this model.

We have modelled both minimum and maximum funding needs scenarios for the overall malaria R&D funding need, as well as for each product type.

uncertainty multiplier (of 10% in the minimum scenario, and 20% in the maximum scenario) were applied to the cost estimates. The uncertainty multiplier has been a feature of this modelling effort since the Global Malaria Action Plan in 2008, intended to account for the "inherent uncertainty in predicting time and costs associated with technology development". There is some question whether this remains appropriate given the increased sophistication of the costing, but to be consistent with the approach taken previously – and to reflect the fact that the assumptions are otherwise based on a perfectly coordinated and optimally managed research effort – we have preserved the multiplier subject to further discussion.

In light of each of the above considerations, "funding need" as it is discussed in the findings below should be understood as including 1) the cost required to achieve the stated targets for drugs, endectocides, and vector control products, plus 2) the cost required to advance the vaccine and biologics R&D targets through 2030, plus 3) the cost of delivering malaria basic research at levels consistent with the last twelve years of available funding data for this category (2007-2018). Nuances of product-specific changes and modelling outcomes are addressed in the following sections.

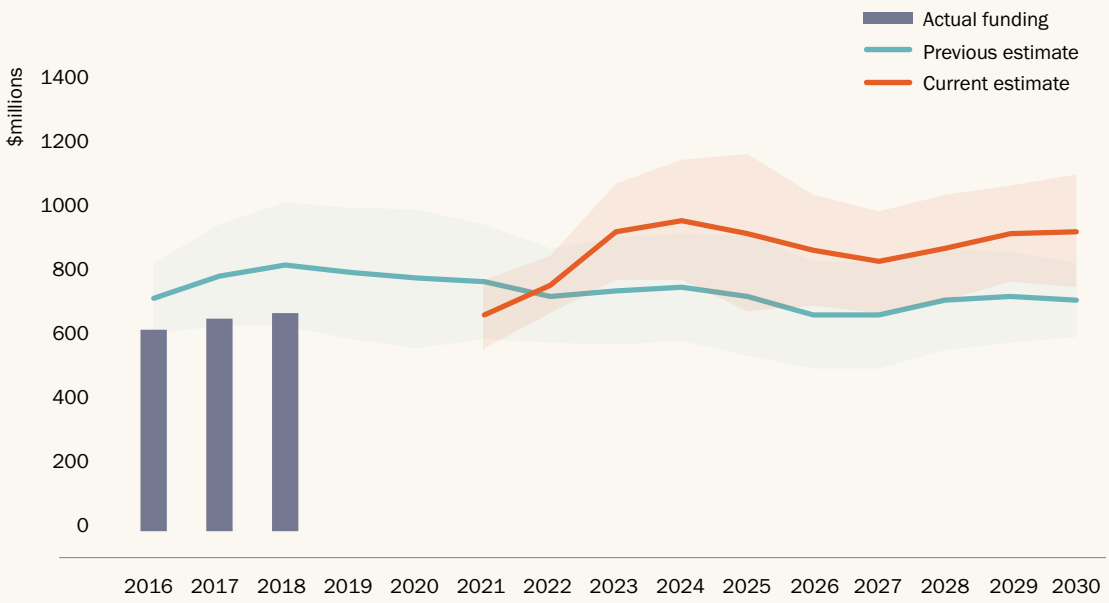
Findings

Overall malaria R&D funding need (2021-2030)

A total of $8,515m (range: $6,952m–$10,078m) is projected to be needed for research and development during the period 2021-2030, representing an average annual investment of $851m ($695m–$1,008m).

This is 20% higher than the previous estimate for the same period of $7,090m ($5,530m–$8,651m). Much of this increase, however, is driven by new priority areas not included in the previous cost modelling; key contributions to the change are described in detail below. Actual annual global investment in malaria R&D from 2016-2018 followed the required trend identified by the previous funding need estimate, although it reached only the minimum bound of the forecast range.

Figure 1: Comparison of malaria R&D funding requirement estimates and actual investment



Malaria R&D funding need by product (2021-2030)

Table 1 and Figure 2 provide a breakdown of the R&D funding needs by product and target. Taking the midpoint values of the projected funding need, the largest funding need is for vaccines ($2,715m, 32% of overall funding), followed in order by basic research ($1,904m, 22%), drugs ($1,609m, 19%), vector control products ($1,082m, 13%), biologics ($759m, 8.9%), endectocides ($259m, 3.0%), and diagnostics ($187m, 2.2%).

At the target level, the cost of advancing vaccine Target 3 (transmission-blocking vaccine for *Plasmodium falciparum* (SSM-VIMT)) represents the highest funding need at $1,013m between 2021 and 2030, which is 37% of the total funding need for vaccines and 12% of the overall malaria

R&D funding need. The two targets with the next highest funding needs are TCP 1 for drugs (three new chemical entities (NCEs) that clear asexual blood-stage parasitaemia) at $871m (54% of funding need for drugs and 10% of overall malaria R&D funding need), followed by vaccine Target 4 (transmission-blocking vaccine for P. vivax) at $747m (8.8% of overall malaria R&D funding need). The funding requirements for each target are illustrated in *Annexe II*.

The funding estimate ranges for some products are fairly wide. The difference between the minimum and maximum funding estimates for drugs, for example, is $687m and for vaccines it is $837m.

Table 1: Malaria R&D funding needs range by product

$ millions	Minimum	Midpoint	Maximum
Basic research	1,824	1,904	1,984
Drugs	1,266	1,609	1,953
Vaccines	2,296	2,715	3,134
Diagnostics	103	187	271
Biologics	625	759	893
Endectocides	97	259	420
Vector control	741	1,082	1,424
Total	**6,952**	**8,515**	**10,078**

Figure 2: Malaria R&D funding needs by product and target

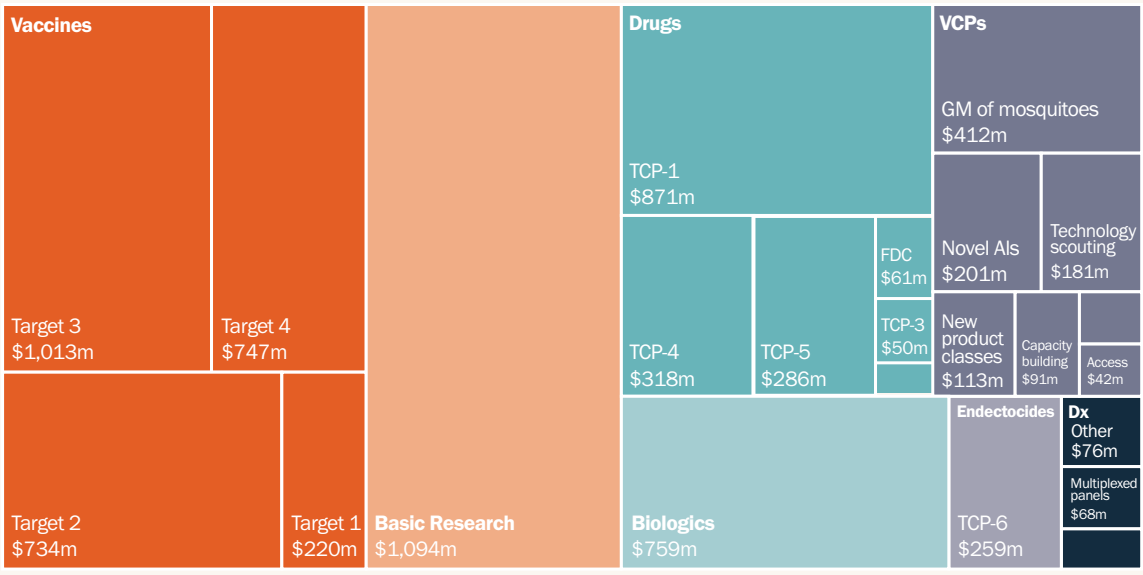
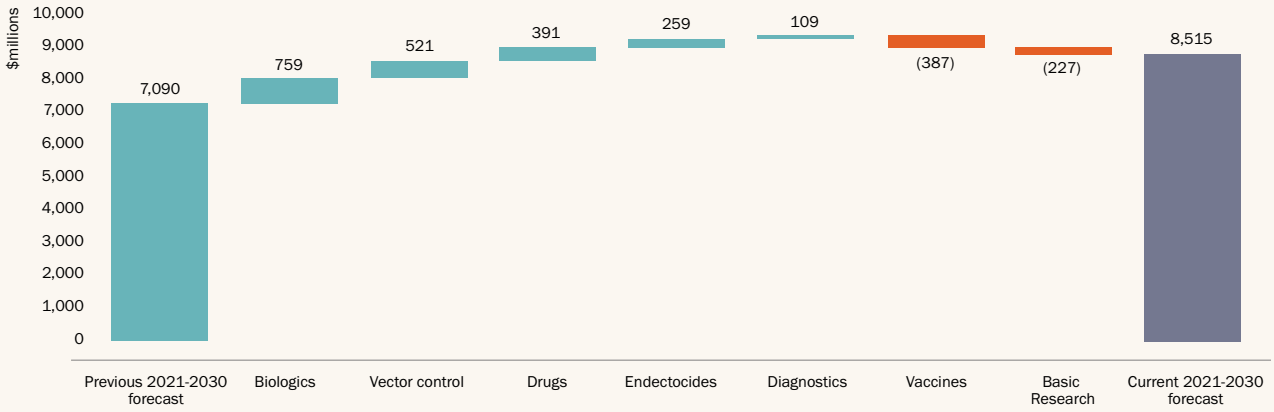


Figure 3 presents the change in product-specific funding need compared to the estimates included in the original GTS. The overall increase in the estimated funding needed from 2021-30 was $1,424m. This included $759m for biologics and $259m for endectocides (neither of which were included

in the original GTS estimate), a $521m increase for VCPs (in large part due to the estimate of the cost of genetic approaches to vector control, a field of research which has advanced significantly since 2014), a $391m increase for drugs (in part due to the addition of an explicit target for TCP 5: molecules that block transmission targeting parasite gametocytes), a $109m increase for diagnostics, and decreases of $387m and $227m for vaccines and basic research respectively.

Figure 3: Difference between previous and current estimate



Basic Research

Model adjustments, targets and assumptions

Because of the nature of basic research, it is not possible to identify or cost all component activities. However, key research activities accounted for in the assumptions include:

- Natural history and epidemiology
- Immunology of disease
- Biology of disease
- Biochemistry of the pathogen
- Genetics of the pathogen
- Bioinformatics and proteomics
- Pathophysiology and disease symptoms
- Vector biology, biochemistry, and genetics

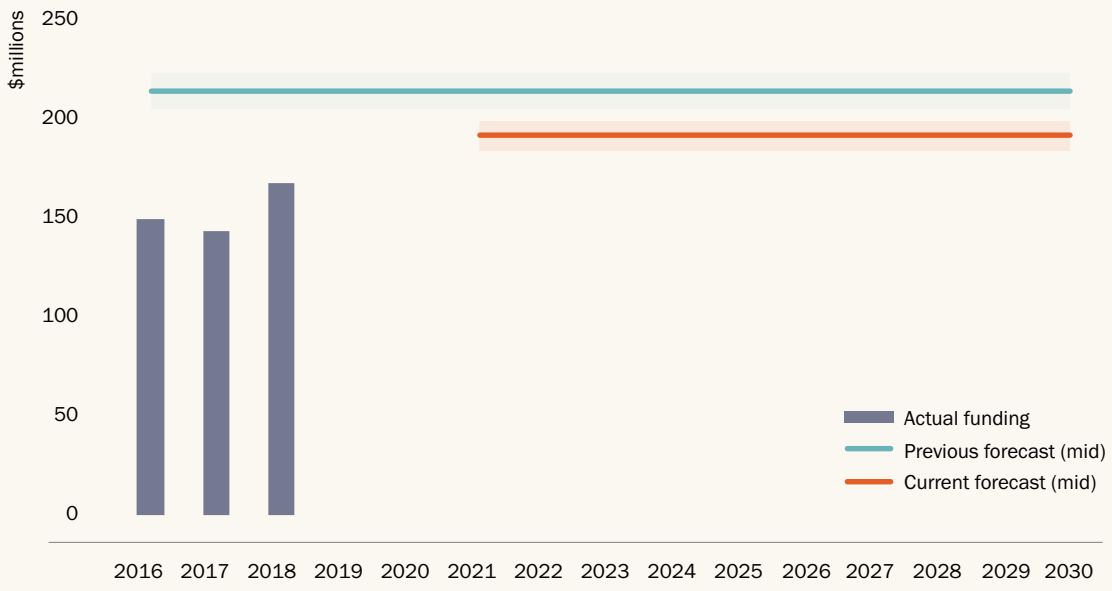
Funding estimates

The model estimates that $1,904m (range: $1,824m–$1,984m), equivalent to $190m p.a. ($182m–$198m) will be required to support basic research.

Annual funding projections for basic research were calculated using an average of the twelve available years of historical data (G-FINDER malaria R&D data from FY2007-2018), with projected investment assumed to be constant in real dollar terms for the duration of the model. This results in basic research funding accounting for 23% of total R&D funding over the 2021-2030 period, which is broadly consistent with the share of global malaria R&D funding that has historically been directed to basic research (26% over the 2007-2018 period).

The updated funding estimate for basic research is 11% lower than the previous cost estimate of $2,131m, which was based on an average of the five preceding years of malaria basic research funding data. However, the updated estimate remains above the long-term average – and around 14% higher than the $167m actually invested in basic research in 2018 – due to the application of the uncertainty multiplier.

Figure 4: Comparison of basic research funding requirement estimates and actual investment



Drugs

Model adjustments, targets and assumptions

The original model, as it pertained to malaria drugs, was constructed around the foundation of target candidate profiles. Whilst being restricted by using the same model foundations, we have worked to ensure that the current malaria drugs R&D agenda – which is focused more on the overarching target product profiles (TPPs) – is the true driver of the cost projections. A full re-development of the underlying model structure was outside the scope of this update but may warrant future consideration. It is important to note that while the priorities and targets for the updated modelling

are still expressed at the TCP level, it is not the case that the model assumes these will be advanced through to approval as single compounds; targets refer to the date at which a drug containing a given NCE first receives approval by a stringent regulatory authority.

Table 2 shows both the original and current TCP-specific targets; changes reflect evolution of the TCPs and TPPs since the previous modelling work. Notable changes include the removal of TCP-2 (molecules with long duration of action), as well as the addition of a new explicit target for TCP-5: molecules that block transmission by targeting parasite gametocytes. The model also continues to reflect modelled costs of reformulations, fixed-dose combinations (FDCs) and label extensions tied to the overall number of NCEs.

Table 2: Drug priorities and targets

Priority		Original target	Current target	Notes
TCP-1	Molecules that clear asexual blood-stage parasitaemia	2 x NCEs by 2022 1 x additional NCE by 2027	3 x NCEs by 2030	Previously specific to compounds with rapid effect ('fast clearance') but now revised to no longer specify speed of effect, and assumes all candidates have been selected for long duration of action (previously TCP2)
TCP-3	Molecules with activity against hypnozoites (mainly P. vivax)	1 x NCE by 2022 1 x additional NCE by 2027	1 x NCE by 2022	2022 target has been achieved with approval of tafenoquine. Post-registration/Phase IV costs for tafenoquine are included in model projections. Next generation target has been removed
TCP-4	Molecules with activity against hepatic schizonts	1 x NCE by 2022	1 x NCE by 2030	Target revised, as new drugs for TPP-2 not restricted to novel molecules for causal prophylaxis; see FDCs and label extensions below
TCP-5	Molecules that block transmission (targeting parasite gametocytes)	N/A	1 x NCE by 2030	This was previously TCP 3b, but no explicit target was included
Reformulations, FDCs and label extensions		1.5 for every 2 NCEs (75% of NCE target)	1.5 for every 2 NCEs (75% of NCE target)	This existing model category accounts for various additional priorities elucidated in the GMP working paper and malERA refresh, including the combination of approved individual drugs into new combinations for prophylaxis, reformulation of new small molecule drugs for paediatric populations, and label extension of novel drugs to special populations such as pregnant women
Drugs for severe malaria		No explicit target	No explicit target	Includes novel pipeline candidates being developed specifically for this indication, as well as secondary testing of molecules being developed for other indications

There is a question about whether the explicit target of an NCE for anti-gametocidal transmission blocking activity (TCP-5) should in fact be included, given that all new molecules will be profiled for transmission blocking activity, but none would be deployed purely for its impact on gametocytes. There is also a question as to whether an explicit target of an NCE for severe malaria should be included (noting that despite the real-world expectation that the intravenous formulation of KAE609 may be expected to launch in 2028-29, the paucity of candidates in the pipeline specifically for this indication mean that on a risk-adjusted basis there is minimal projected investment in this area, and no NCE expected by 2030).

We believe the second and third pillars of the proposed new approach to developing drugs for malaria prophylaxis – "Re-combine" (launch 2024-2029) and "Develop" (launch after 2030) – are addressed by the current model, but this approach was being discussed at a GMP-led workshop in December 2020. The conclusions of this may have a direct bearing on the drug-specific assumptions used in the model and may warrant revisiting.

The assumptions used to calculate the cost to reach the drug targets have been updated following consultation with key experts (see *Annexe I*) and comparison against benchmark data. Notably, the cost assumptions relating to Phase III increased (from a range of $35-41m to a range of $49-71m), as they did for reformulations, FDCs and label-extensions (from a range of $5.7-13m to a range of $11-26m). Costs for Phase IV, IIa and Discovery have also increased. The assumption used to estimate the maximum time it would take for candidates to go through reformulations, FDCs and label extension development was increased from 3 to 5 years. The probability of technical success (PTS) of Phase IIb was lowered from 75% to 67% (representing the midpoint between the previous 75% PTS and the 60% quoted in Burrows et al., 2017, based on MMV's historical success 2009-14).

Table 3: Drug assumptions

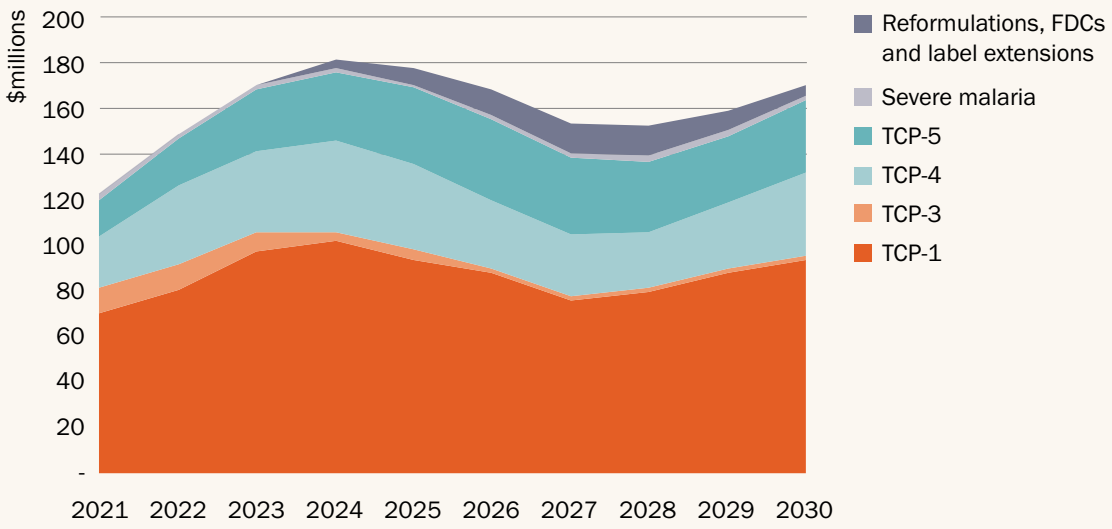
R&D activity	Duration, years		Cost, $m		Probability of progression to next stage
	Minimum	Maximum	Minimum	Maximum	
Discovery	Annual		4.0	10	-
Preclinical	1.5	3	2.1	2.4	55%
Phase I	1	2	1.7	2.0	60%
Phase IIa	1.5	2	2.6	4.0	30%
Phase IIb	3.5	4	12	16	67%
Phase III	2.5	4	49	71	73%
Phase IV	5	5	17	29	98%
Reformulations, FDCs and label extensions	3	5	11	26	-

Funding estimates

The model estimates that in order to meet the drug targets, $1,609m will be needed between 2021 and 2030 (range $1,266m– $1,953m), equivalent to $161m p.a. ($127m– $195m).

TCP-1, which targets the development of three NCEs (compared to 1 NCE for each of TCPs 3, 4 and 5) accounts for 54% of the costs. The achievement of TCP-5 is highly reliant on new research programmes, with no pure TCP-5 candidates currently in development. As a result, we have modelled a sizeable backfill of discovery investment and staggered the illustrative preclinical programme start dates over the next six years. It is also worth noting that the funding need explicitly attributed to severe malaria (see Figure 5 below) isn't a true reflection of the total investment relevant to this priority, some of which is captured under TCP-1.

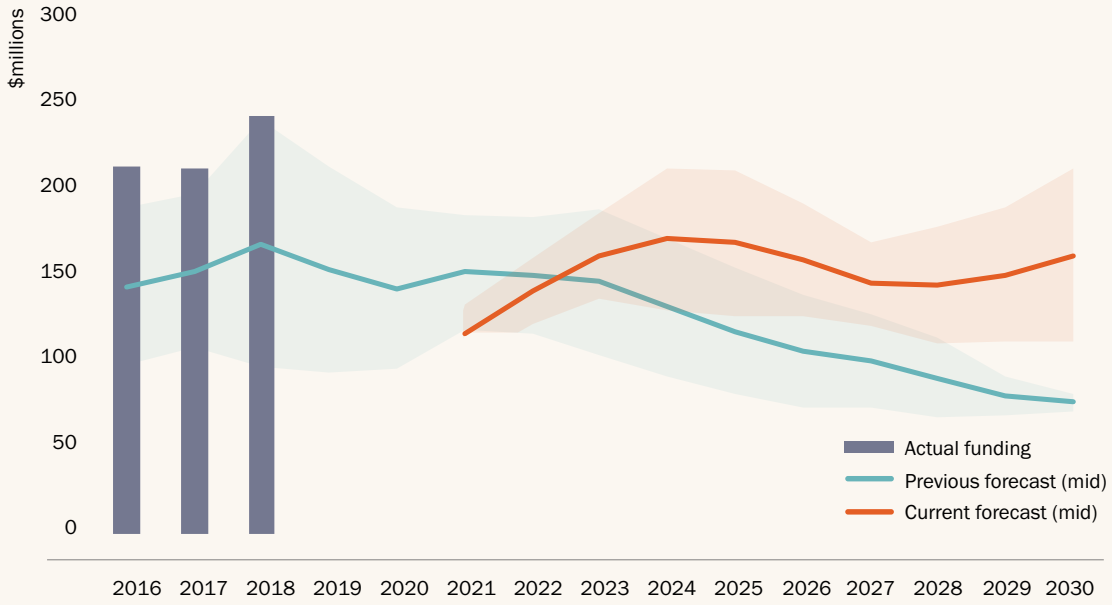
Figure 5: Drug R&D estimated annual funding requirements by target



There are two peaks in the funding profile: one in 2024 which is driven by development costs for TCP-1, TCP-4 and TCP-5 and another after the forecast period (2031) associated with backfill-driven costs for TCP-1 and TCP-4. The annual requirements drop away after 2031.

The projection for drug R&D investment is 32% higher than the previous forecast of $1,218m. As noted above, the major drivers of this increase were the inclusion of new targets (and resultant increases in reformulations, FDCs and label extension), as well as increased assumptions for Phase III and IV development costs. Also note that the previous projection suggested a significant tailing off of required investment over the course of 2020-2030 which was perhaps over-optimistic. The current modelling reflects a more constant year-on-year funding need.

Figure 6: Comparison of drug R&D funding requirement estimates and actual investment



Vaccines

Model adjustments, targets and assumptions

The malaria vaccine targets remained unchanged from the original model.

The projected costs for Target 1 included in the model relate to the ongoing pilot implementation of RTS,S (due to be completed by 2023) and further evaluation to determine the potential for increased efficacy with alternative dosing regimens, or in other epidemiological settings and populations.

Some of the most advanced 'next generation vaccines' (Target 2) are aligned more closely with the RTS,S profile than that of a true second-generation vaccine (as defined in the targets). It is possible that another target category between RTS,S and a true second-generation is needed for RTS,S-like vaccines with certain preferable attributes, such as cost of manufacture. Additionally, this target incorporates vaccines targeting clinical malaria and/or infection, but no distinction is made in the assumptions for cost, probability of success or duration for these two distinct indications. On a risk-adjusted basis the approval of a second-generation vaccine by 2030 has a probability of less than 100%, but two successful vaccines could be expected by 2035.

Table 4: Vaccine priorities and targets

Priority		Target	Notes
Target 1	First-generation *P. falciparum* vaccine with 50% protective efficacy against severe disease and death, lasting longer than one year	By 2015	Partially achieved with the positive scientific opinion given to RTS,S, and noting in retrospect that severe disease and death may not have been reasonable efficacy targets in a disease such as malaria.

Table 4: Vaccine priorities and targets

Priority		Target	Notes
Target 2	Second-generation *P. falciparum* vaccine (with or without components that target *P. vivax*) with protective efficacy of more than 75% against clinical disease and/or infection, providing protection for longer than two years (PE-VIMT or BS-VIMT or multi-stage VIMT)	By 2030	Includes all non-RTS,S pre-erythrocytic and blood stage candidates in the current pipeline.
Target 3	Transmission-blocking vaccine for *P. falciparum* (SSM-VIMT)	By 2030	Not on track to be achieved by 2030
Target 4	Transmission-blocking vaccine for *P. vivax* (SSM-VIMT)	By 2030	Not on track to be achieved by 2030

Following consultation with experts and comparison against benchmark data, we made changes to the probability of technical success assumptions for sexual stage vaccines to reflect greater certainty in early stages of development (assisted by recent advances in pre- and early clinical testing, including the development of CHMI-transmission models for both *P. falciparum* and *P. vivax*), but less certainty in later stages compared to pre-erythrocytic or blood stage vaccines; in the previous modelling, sexual stage vaccines had the same PTS as PE/BS vaccines for phase IIb trials, and a higher PTS for Phase III (which we believe to have been an error). The PTS assumptions for Phase Ia and Ib, which were previously both 20%, increased to 40% and 50% respectively (resulting in an overall Phase I PTS of 20%). We reduced the Phase IIb PTS from 50% to 38% and the Phase III PTS from 70% to 60%.

We increased two cost assumptions for vaccines: preclinical research for pre-erythrocytic or blood stage vaccines was changed from a range of $0.06m-$0.6m to $2.3-5.7m and Phase Ia/IIa increased from $0.9m (both min and max) to $1.7-2.1m. We created a Phase IV cost assumption of $72-114m for use only for RTS,S.

We reduced the duration assumptions of Phase Ia and Ib by one year, due to the advances outlined above.

Table 5a: Vaccines assumptions, pre-erythrocytic or blood stage vaccines

R&D activity	Duration, years		Cost, $m		Probability of progression to next stage
	Minimum	Maximum	Minimum	Maximum	
Discovery	Annual		4.4	7.2	-
Preclinical	5	5	2.3	5.7	53%
Phase Ia/IIa	1	1	1.7	2.1	25%
Phase Ib	2.5	4	1.1	4.6	88%
Phase IIb	5	7.5	17	23	50%
Phase III	4	5	160	320	60%
Phase IV	5	8	34	114	85%
Phase IV (RTS,S)	5	8	72	114	85%

Table 5b: Vaccines assumptions, sexual stage vaccines

R&D activity	Duration, years		Cost, $m		Probability of progression to next stage
	Minimum	Maximum	Minimum	Maximum	
Discovery	Annual		4.3	7.2	-
Preclinical	5	5	2.3	5.7	30%
Phase Ia	2.5	4	4.3	11	40%
Phase Ib	2.5	4	4.3	11	50%
Phase IIb	5	7.5	57	114	38%
Phase III	4	5	343	343	60%
Phase IV	5	8	34	114	85%

We found that on a risk-adjusted basis the current pipeline of Target 2 vaccines is likely to result in more products than required by the target (albeit not by 2030). Rather than bear the full cost of the development of all of those candidates (allowing for attrition), we expect that there will be rationalisation and down-selection. We therefore set the model to terminate the development of some candidates before starting Phase IIb.

Funding estimates

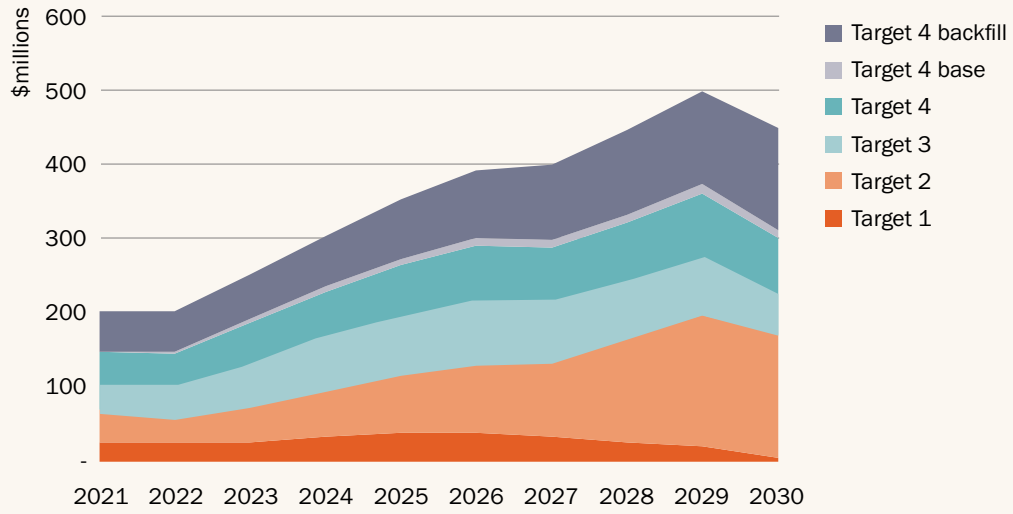
The model estimates that $2,715m will be needed for vaccine research between 2021 and 2030. The range is $2,296m to $3,134m, with an average annual cost of $272m.

However, on a risk-adjusted basis, the probability of reaching Targets 2, 3 and 4 is less than 100%, so this shouldn't be interpreted as the "price tag" for achieving the targets. Indeed, based on the current state of the R&D pipeline, neither a transmission blocking vaccine for *P. falciparum* (Target 3) nor a transmission blocking vaccine for *P. vivax* (Target 4) is expected even by 2035. The modelled funding need for vaccines should instead be interpreted as the investment required during the period 2021-30 to advance towards Targets 2, 3 and 4 as rapidly as possible. Significant additional investment will also be required beyond 2030, especially for Targets 3 and 4.

The modelled funding need for vaccines should be interpreted as the investment required to advance towards Targets 2, 3 and 4 as rapidly as possible rather than a price tag.

With only one currently active candidate (yet to enter human trials), it is not clear that Target 4 remains a realistic priority within the timeframe of the GTS. We have presented the cost projections of the backfill for this target separately to show how costs could vary with and without this as an explicit target.

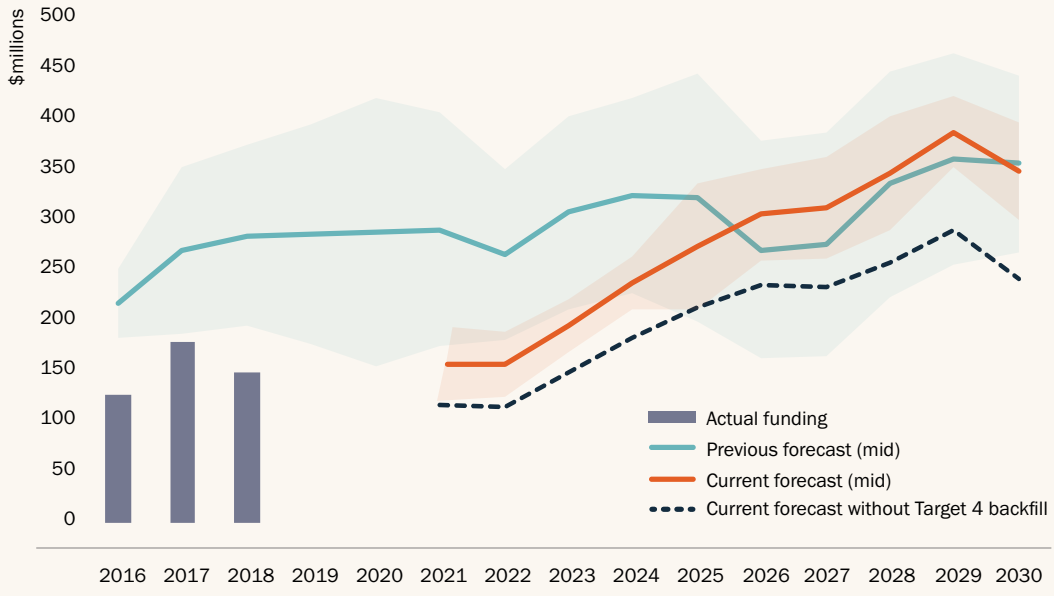
Figure 7: Vaccine R&D estimated annual funding requirements by target



The funding requirements in the near future are in line with what has been invested in recent years but the projection for funding rises sharply from 2022 if all targets are to be pursued. Funding requirements for Targets 2 and 4 continue to increase after 2030.

The projected costs between 2021 and 2030 are 12% lower than the previous estimate of $3,102m. This is partly because costs have been shifted later (due to slower progress than anticipated in the previous model, reflected in the current state of the vaccine pipeline), and thus fall outside the 2021-2030 term. This is reflected below in Figure 8. Notably, the range of the forecast has narrowed as a result of the increases in PTS for Phases Ia and Ib.

Figure 8: Comparison of vaccine R&D funding requirement estimates and actual investment



Diagnostics

Model adjustments, targets and assumptions

A number of changes have been made to the targets used in the earlier version of the model, including the removal of positive control wells, RDT quality control at the clinic level, and serological screening tests from the list of modelled priorities, as these were no longer identified as priorities (noting that the previous model projected no costs beyond 2020 for these targets).

New priorities included in the updated model were: diagnostics to identify hypnozoites; population screening for *P. vivax* infection surveillance; point-of-care diagnosis of sub-clinical *P. vivax* infection; diagnosis of *P. vivax* malaria acute infection and the creation of stable, valid, specific and sensitive RDTs not dependent on Pfhrp2/3.

Diagnostics have been modelled without explicitly enumerating the probability of success.

Table 6: Diagnostics targets and assumptions

R&D activity	Target date		Cost, $m		Notes
	Minimum	Maximum	Minimum	Maximum	
RDTs that detect and differentiate all Plasmodium species	2023	2025	3.0	10	
Stable, valid, specific and sensitive RDTs that do not depend on Pfhrp2/3	2023	2023	5.0	5.0	**Newly added**
Diagnosis of *P. vivax* malaria acute infection	2022	2023	5.0	7.5	**Newly added**
Point-of-care diagnosis of sub-clinical *P. vivax* infection	2028	2030	4.0	8.0	**Newly added; starts in 2025**
Highly sensitive point-of-care tests for the rapid detection of low-density, sub-clinical *P. falciparum* malaria infections	2023	2025	10	13	
Diagnostics to identify hypnozoites	2025	2027	10	13	**Newly added**
Affordable, simple, and accurate point-of-care tests for G6PD-deficiency	2024	2026	5.0	7.5	
Multiplexed panels for common causes of disease to support clinical care for broad range of pathogens, including malaria	2025	2030	10	100	
Non-invasive/self-administered diagnostic tests	2025	2030	30	42	
Automated microscopy	2023	2023	2.0	2.0	
Population screening for *P. vivax* infection surveillance	2022	2023	1.0	2.0	**Newly added**
Molecular assays for antimalarial drug resistance surveillance	2025	2030	5.0	10	

Table 6: Diagnostics targets and assumptions

R&D activity	Target date		Cost, $m		Notes
	Minimum	Maximum	Minimum	Maximum	
Infectivity/gametocyte diagnostics					**Newly added; no estimates available for scale of investment required**
POC/health system falsified drug screening					**Newly added; no estimates available for scale of investment required**

Most of the estimates for diagnostics R&D activities assume a well-coordinated global R&D effort that results in exactly the necessary number of products.

While it is not clear that automated microscopy remains a consensus priority, an allowance has been included in the overall estimate for the cost of concluding development and pilot implementation for solutions currently in – or recently emerged from – the pipeline.

We received mixed feedback on the inclusion of infectivity/gametocyte diagnostics and point-of-care (POC)/health system falsified drug screening tools as research priorities. As we currently lack meaningful estimates for the cost of meeting either of these targets, we have included them as placeholders in the table as a basis for future research and discussion, but do not attempt to include their development costs in our overall funding estimate.

The development of high-throughput mosquito assays has been included as a priority under the vector control product area, rather than under diagnostics, whereas the development of molecular assays for antimalarial drug resistance surveillance has been retained as a priority under diagnostics (as per the original projections).

Most of the estimates for diagnostics R&D activities assume a well-coordinated global R&D effort that results in exactly the necessary number of products – often just one or two new unique tools – per target. The large number of disparate actors in this space means that actual global investment would likely not be allocated optimally across the targets and would therefore need to be higher overall than our estimate in order to meet every target.

Funding estimates

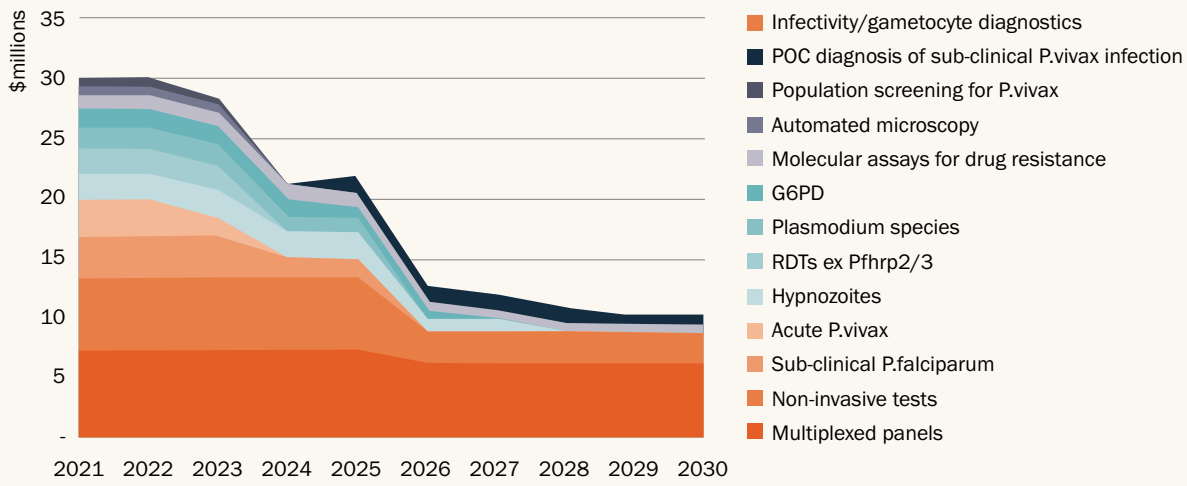
The model's midpoint estimate suggests that $187m will be needed for diagnostics research between 2021 and 2030, an implied annual requirement of close to $30m between 2021 and 2023, gradually declining to around $10m a year between 2028 and 2030 once the majority of the targets have been met.

The lower-bound estimated total is $103m, with an upper bound of $271m. This range is heavily driven by the $90m difference between the minimum and maximum cost assumptions for multiplexed diagnostics. This reflects the decision to model two distinct approaches to meeting this target: a point of care biomarker plus malaria combi-test in the minimum scenario, and in

the maximum scenario a multiplex multi-analyte diagnostic platform (MAPDx) for broad range of pathogens, including malaria.

There are two targets that together account for almost two-thirds of the diagnostic funding need, as measured at the midpoint: multiplexed diagnostics ($68m, 36%) and non-invasive/ self-administered diagnostic tests ($43m, 23%). However, as noted above, there are two distinct approaches modelled for multiplexed diagnostics. In the minimum scenario, they account for only 11% of the total diagnostics projection ($11m).

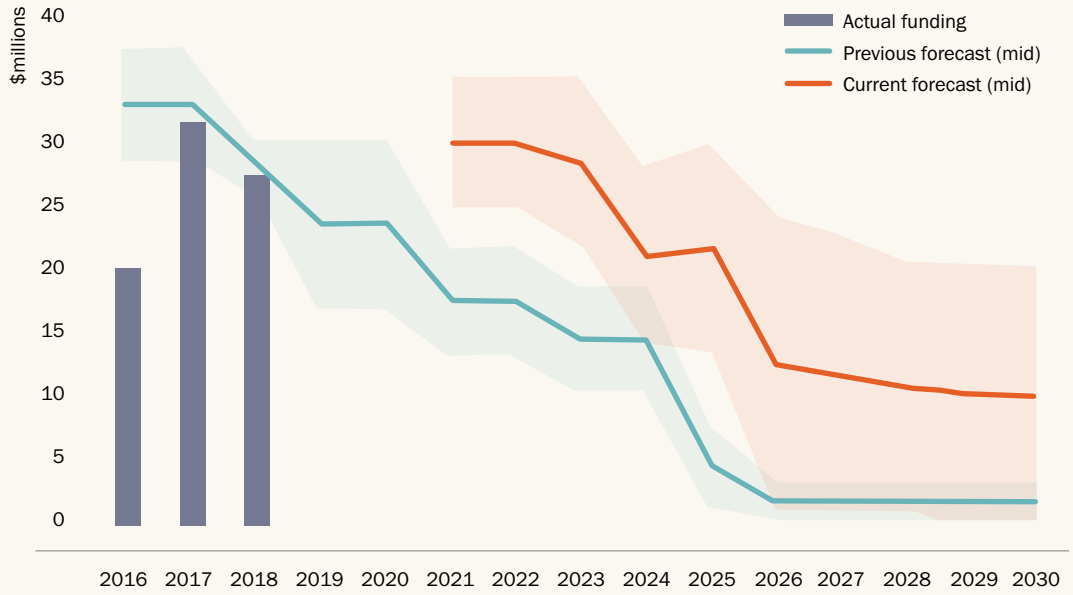
Figure 9: Diagnostic R&D estimated annual funding requirements by target



The previous model forecast a funding need for diagnostics of $78m for the period 2021-2030, with annual R&D investment dropping to negligible levels in the latter half of the decade. The updated forecast of $187m is more than double (2.4 times) the previous estimates, driven in part by the addition of new targets which were not included in the previous analysis, but also reflecting extensions to the expected dates to achieve some previously modelled priorities. It is important to note that these projections do not account for the funding required to achieve two of the newly added priorities (infectivity/gametocyte diagnostics, and POC/health system falsified drug screening) as no reliable estimates for these costs were available. Actual global funding for malaria diagnostic R&D in 2017 and 2018 was well aligned with the previous projections of funding required.

Actual global funding for malaria diagnostic R&D in 2017 and 2018 was well aligned with the previous projections of funding required.

Figure 10: Comparison of diagnostic R&D funding requirement estimates and actual investment



Biologics

Model adjustments, targets and assumptions

Targets for biologics R&D – in this case the development of monoclonal antibodies (mAbs) and combinations of recombinant multi-mAb products – are a new inclusion in this updated version of the model. In addition to increased therapeutic applications across a number of chronic, non-communicable diseases in the years since the previous malaria R&D targets were agreed, biologics have received increased attention for their use in countering infectious diseases, including malaria. With both therapeutic and preventive applications (including the potential for transmission-blocking activity) and sharing attributes with both drugs and vaccines, biologics could be considered as a target within either (or both) those product areas. We have opted to include them as a standalone product category.

The single target used for biologics R&D does not distinguish between mAbs for treatment/prophylaxis and mAbs for the interruption of transmission. A target which called for the creation of at least one product under *each* of these indications would lead to a significant increase in required funding, and require additional assumptions on cost, duration and probability of success that distinguish between the two areas.

Table 7: Biologics priorities and targets

Priority	Previous target	Current target	Explanation of change
Development of monoclonal antibodies (mAbs) and combinations of recombinant multi-mAbs products	N/A	1 x new mAb by 2030	No distinction is made between mAbs for treatment and prophylaxis vs mAbs for the interruption of transmission On a risk adjusted basis, the model does not forecast a new mAb by 2030

The estimates of cost and probability of technical success for the target we identified are derived from the treatment of biologics in the P2I model, with malaria-specific adjustments made to the costs and probabilities at the preclinical phase.

Table 8: Biologics assumptions

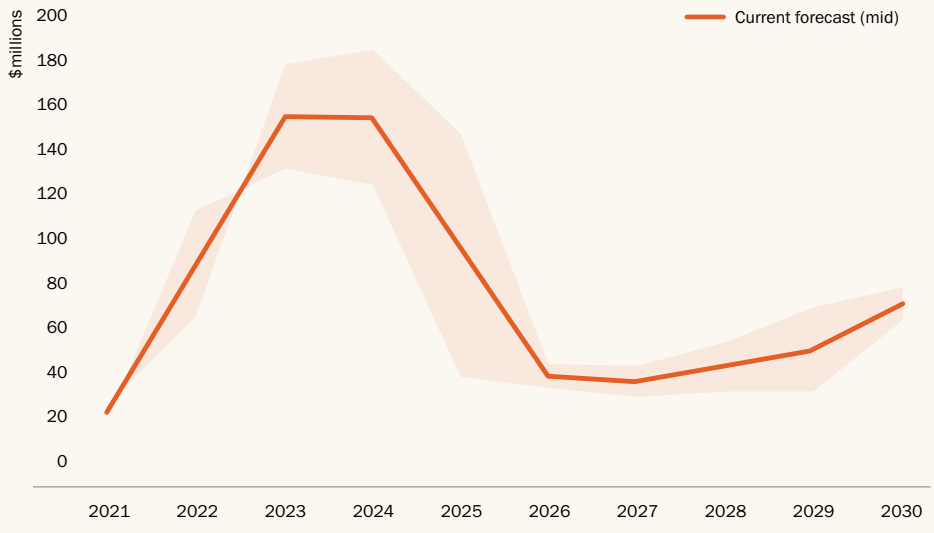
R&D activity	Duration, years		Cost, $m		Probability of progression to next stage
	Minimum	Maximum	Minimum	Maximum	
Discovery	-	-	4.3	7.2	-
Preclinical	3	4	12	17	41%
Phase Ia/Ia	1	2	0.9	1.8	55%
Phase Ib	1	2	1.1	4.6	80%
Phase IIb	2.2	4.2	11	18	33%
Phase III	2.5	4	126	155	60%
Phase IV	5	8	16	26	85%

Funding estimates

The model estimates that $759m ($625m–$893m) will be required for malaria biologics. Expert opinion suggests that the target could be achievable with the products that are currently in development, but with a pipeline of just four products, on a risk-adjusted basis, the model forecasts that the target won't be met by 2030. As such, it incorporates relatively rapid scaling up of the pipeline of research and investment compared to current levels. The modelled funding requirement in 2021 is $24m (as compared to $1.7m in reported funding in 2018) and is predicted to peak at over $150m per year in both 2023 and 2024, before falling to $40m in 2026. Beyond 2030, the funding requirement would need to rise to accommodate the development costs of the preclinical programmes that theoretically begin in 2021.

The vast majority (80%, $613m) of the forecasted cost is to fund new research programmes, rather than continue the development of existing candidates. The forecast funding needs for the existing candidates is $146m.

Figure 11: Biologics R&D estimated annual funding requirements



Endectocides

Model adjustments, targets and assumptions

This product area is newly included in the updated model. In addition to the repurposing of ivermectin – for which R&D efforts are well advanced, with a recently published Roadmap outlining the pathway to availability by 2024 – we have also included a target for an additional new chemical entity by 2030, despite the fact that there is not a definite global consensus on this as a priority for malaria R&D. Further consultation is required to reach consensus on the role and importance of next generation molecules, such as isoxazolones.

Table 9: Endectocide priorities and targets

Priority		Previous target	Current target	Notes
TCP-6	Molecules that block transmission by targeting the insect vector	N/A	Repurposing of ivermectin 1 x additional NCE by 2030	Newly added

Due to the lack of any validated assumptions specific to endectocide development, we have used the standard costing assumptions for drugs to forecast the funding requirements for both ivermectin and NCEs. The forecast could be improved by incorporating more accurate activity-based costing of the remaining development work for repurposing ivermectin (including explicit estimates for additional studies on the safety of ivermectin in children <15 kg and/or pregnant women post-2024, if required, or the cost of studies to evaluate ivermectin in conjunction with seasonal malaria chemoprevention or NTD control programmes), and by reviewing the assumptions for the development of the NCEs, to better reflect the unique development pathway for endectocides. There may also be benefit in attempting to distinguish between truly unprecedented next-generation molecules and drugs from classes with established veterinary use, such as the isoxazolones.

Table 10: Endectocide assumptions

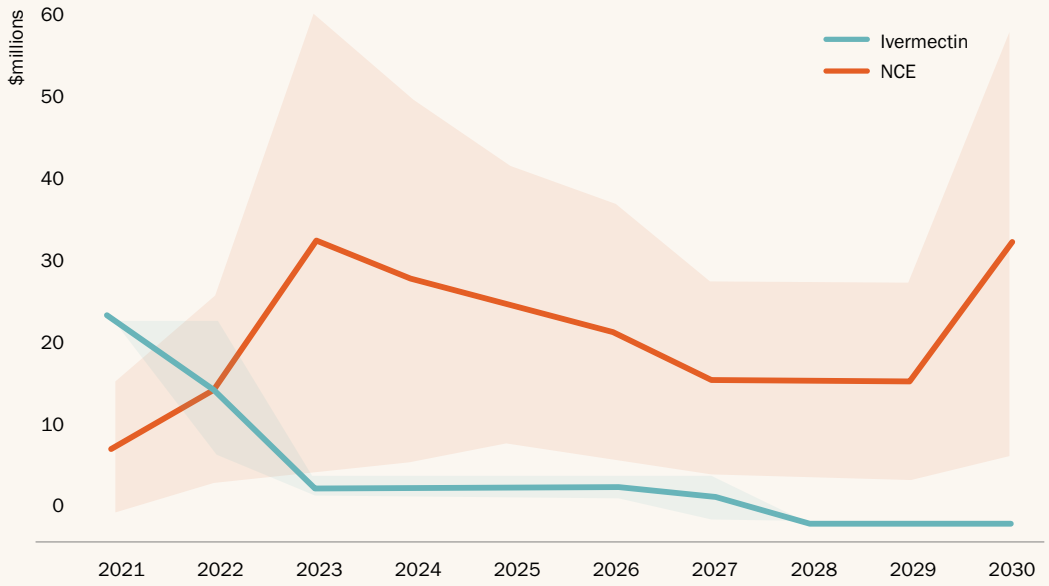
R&D activity	Duration, years		Cost, $m		Probability of progression to next stage
	Minimum	Maximum	Minimum	Maximum	
Discovery	Annual		4.0	10	-
Preclinical	1.5	3	2.1	2.4	55%
Phase I	1	2	1.7	2.0	60%
Phase IIa	1.5	2	2.6	4.0	30%
Phase IIb	3.5	4	12	16	67%
Phase III	2.5	4	49	71	73%
Phase IV	5	5	17	29	98%

Funding estimates

We estimate that meeting the target for endectocides will cost $259m ($97m–$420m) between 2021 and 2030. However, the midpoint estimate for endectocide funding requirements is somewhat misleading as it combines two elements with vastly different ranges, as illustrated in Figure 12: the repurposing of ivermectin ($56m; $42-70m) and the development of new NCEs ($203m; $55m-$203m). We note that much of the funding required for trials to support the repurposing of ivermectin has already been secured. Costs for next-generation formulations of ivermectin (e.g. injectable or oral ultra-long acting) are included with other next-generation molecules under the NCE projections.

As with biologics, no targets for endectocides were included in the previous iteration of the model.

Figure 12: Endectocide R&D estimated annual funding requirement



Vector control

Model adjustments, targets and assumptions

Although the underlying research priorities are consistent between WHO's preferred product characteristics (PPCs), the IVCC TPPs, the GMP working paper and malERA refresh, there is some variability in how these priorities are categorised. We have aligned with IVCC's approach where relevant.

There are four groups of targets that have been modelled for VCPs: novel active ingredients (AI) that can be used in LLINs and IRS; new product classes; GM mosquitoes; and ongoing costs associated with product development. There are four elements to the ongoing costs associated with product development in this model, compared to just one in the previous iteration. The development of high-throughput mosquito assays has been included as a priority here, rather than under diagnostics (where it has been discussed in the malERA Refresh and GMP analysis of R&D priorities).

Table 11: VCP priorities and targets

Priority		Previous target	Current target	Notes
AIs		3 by 2022 1 additional by 2030	4 by 2030	
Products using AIs		Not explicitly enumerated	6 by 2030	Development starts after the development of the AIs
AI screening		Ongoing activity	5 years	Model doesn't incorporate any costs for AI development after screening
New product classes		Three new technology paradigms	2 by 2030	Max scenario allows for 4 POC to be tested
Enabling science for product development	Address specific scientific challenges supporting product development (age grading, interaction between mosquito and products, sugar feeding behaviour)	-	Ongoing activity	
Capacity building for product development	Includes support of testing sites in endemic countries, staff training, sustaining GLP certification	-	Ongoing activity	
Technology scouting	Includes identification of technology with potential to be developed in vector control products, surveillance systems and development of information systems	-	Ongoing activity	
Access (excluding market shaping interventions)	Anticipate market entry, modelling, cost effectiveness analysis, global access plan commitments	-	Ongoing activity	
High-throughput mosquito assays		-	-	Newly added
GM mosquitoes		Ongoing activity	Ongoing activity	No specific target

The modelling for VCPs reflects inputs from IVCC who also contributed to the previous forecasts. The AIs and new product classes have been modelled using costs attributed to each phase of the development pathways, but without explicit PTSs. In the case of novel AIs, we have assumed that the four AIs that have been identified by IVCC will all progress through development and will result in six products that will require PQ listing, and two of those will require epidemiological studies. We have incorporated the costs of screening for novel AIs from 2021 to 2025 but not beyond, and we have not included any costs of development for AIs that may be identified through the screening.

We made a significant upwards revision (more than tenfold) in the projected R&D funding need for the genetic modification of mosquitoes.

We have assumed that between two and four new product classes will be tested for proof of concept, but only two will progress through development. Further consultation will be needed to determine to what extent the R&D funding estimates for new product classes is sufficient to accommodate all R&D needs under the outdoor biting and emergency use case PPCs.

The ongoing costs associated with chemical product development have increased substantially since the last modelling took place: from $2.6m-6.7m p.a. to $19m-40m p.a.. Previously, the only ongoing cost that supported product development included in the model was for information systems and tools. In this model we have included estimates for enabling science for product development, capacity building for product development, technology scouting, and access (excluding market shaping interventions), as described in Table 11.

Following a separate consultation, we made a significant upwards revision (more than ten-fold) in the projected R&D funding need for the genetic modification of mosquitoes, reflecting the significant progress in this field since the original estimates were developed, and a commensurate increase in the understanding of the development pathway and its costs, including for field trials.

The model could be improved with greater clarity on the specific stages and costs associated with the development of biological VCPs. The modelling also relied heavily on activities and assumptions related to the work of IVCC and the manufacturers engaging with them directly. The costs associated with R&D investments of players outside of this group are not captured consistently in the model. For example, Oxitec's work is captured in the genetic manipulation assumptions, but assumptions for Syngenta's future R&D investment are not (nor is their work included in the target number of new AIs/tools). A reassessment of the targets, capturing the future R&D intentions of a broader group of VCP players may be warranted.

Table 12: VCP assumptions

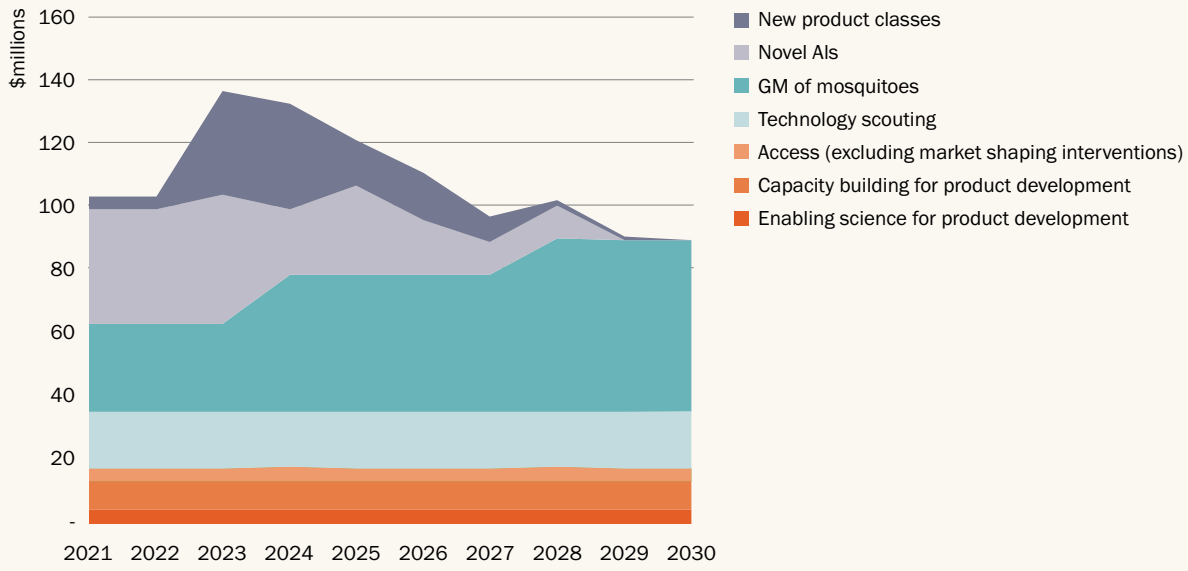
R&D activity		Duration, years		Cost, $m		Notes
		Minimum	Maximum	Minimum	Maximum	
Novel AIs	Screening	5	5	10	30	
	Pre-development	2	3	5	5	
	Development (repurposed)	3	3	5	10	
	Development (novel)	3	3	30	36	
Products using AIs	PQ listing	2	2	0.7	1.3	
	Epi studies	2	2	10	20	
New product classes (ATSBs, etc.)	Proof of concept	2	2	2	2	
	Product development	2	2	10	15	
	Manufacturing platform	2	2	10	20	Concurrent with Product development
	PHV	2.5	2.5	10	20	
	PQ listing	2	2	1	2	
Enabling science for product development		10		2 p.a.	5 p.a.	
Capacity building for product development		10		5 p.a.	10 p.a.	
Technology scouting		10		10 p.a.	20 p.a.	
Access (excluding market shaping interventions)		10		2 p.a.	5 p.a.	
GM mosquitoes	Stage 1	7	3	20 p.a.	25 p.a.	
	Stage 2	3	7	40 p.a.	50 p.a.	
High-throughput mosquito assays		-	-	-	-	No estimates available for scale of investment required

Funding estimates

The model estimates that in order to meet the VCP targets, $1,082m will be needed between 2021 and 2030 (range of $741m to $1,424m), equivalent to $108m p.a. ($74m to $142m).

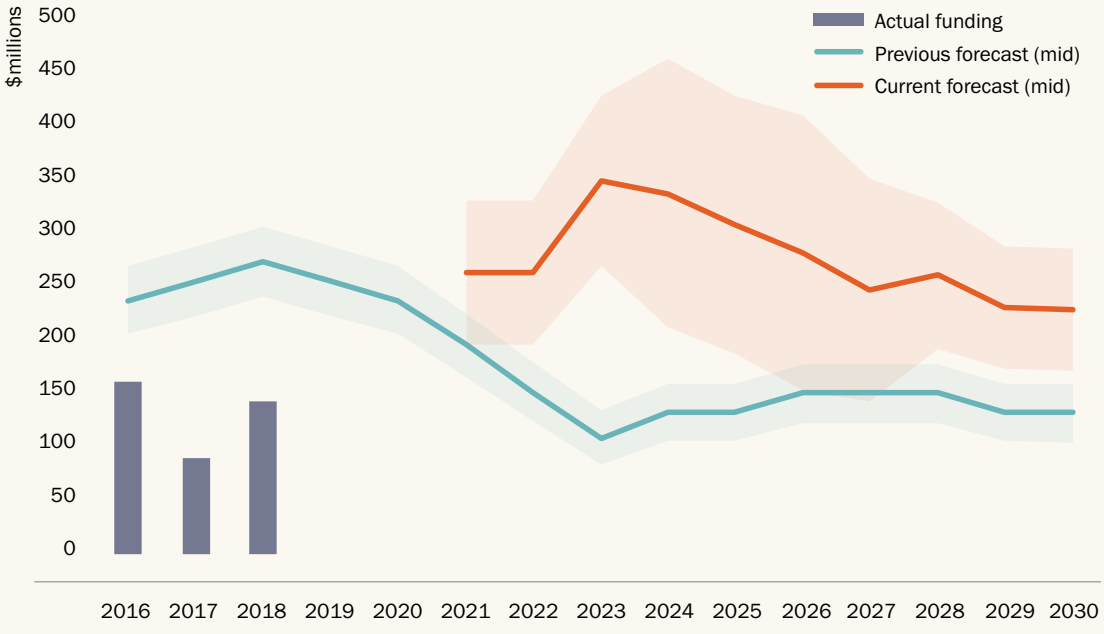
The programme for the genetic modification of mosquitoes accounts for 38% of the costs and has a wide range ($296m to $527m). Novel AIs account for 19% ($201m, $152m-$249m) of the VCP estimate and technology scouting accounts for 17% ($181m).

Figure 13: VCP R&D estimated annual funding requirements by target



The projection for VCP R&D investment is 93% higher than the previous forecast of $562m, driven by the upward revision of the cost assumption for GM mosquitoes and ongoing costs associated with product development (technology scouting, capacity building and enabling science for product development). It should also be noted that global funding, as reported to G-FINDER, did not reach even the minimum bound of the forecast previously made between 2016 and 2018.

Figure 14: Comparison of VCP R&D funding requirement estimates and actual investment



Discussion

This piece of work provides an updated estimate of the funding needed to support malaria R&D for the remaining years of the Global Technical Strategy period (2021-2030), taking into account changes in the malaria R&D landscape in the years since the GTS was first drafted.

A total of $8,515m (range: $6,952m–$10,078m) is projected to be needed for research and development during the period 2021-2030, representing an average annual investment of $851m ($695m–$1,008m). This is 20% higher than the previous estimate for the same period of $7,090m ($5,530m–$8,651m). Much of this increase is driven by new priority areas not included in the previous cost modelling, including biologics and endectocides.

Investment at this level should be expected to achieve the stated targets for drugs, endectocides, diagnostics and vector control products by 2030, as well as to advance the vaccine and biologics R&D pipelines towards their targets as rapidly as possible, though additional investment will be required beyond 2030. It would also sustain funding for malaria basic research between 2021-2030 at levels consistent with the last twelve years of available funding data for this category (2007-2018).

Considerations

At the time the modelling was conducted in late 2020, a number of global stakeholder consultations on various malaria R&D priorities were either underway or planned for 2021. As a result, a number of the assumptions used to inform the model may warrant revisiting in the next 12 months to reflect any notable changes in the global consensus on product-specific R&D priorities. In particular, the overall funding estimate is heavily influenced by priorities and targets for which consensus (and the current pipeline) are limited. These include, in particular, vaccine Targets 3 and 4, as well as the targets for biologics and endectocides.

With WHO-led updates to the vaccine PPC and roadmap planned for 2021, the targets and priorities for malaria vaccine R&D may be revised in the near future; changes to these priorities would have a significant bearing on the overall and vaccine-specific funding need and trajectory between now and 2030.

Perhaps the most notable finding of this particular modelling exercise was the revelation that the currently agreed malaria vaccine priorities for 2030 are not all, from a modelling and forecasting perspective, realistically achievable given what we know about the duration and success of malaria vaccine development efforts to date. Maintaining standalone targets for transmission-blocking vaccines for *P. falciparum* and *P. vivax* should be reviewed carefully by the appropriate stakeholders.

Up for discussion should be the huge price tags and low probabilities of success of pursuing transmission-blocking vaccines (Targets 3 and 4), as well as their commercial viability. In addition to the significant costs associated with advancing vaccines Targets 3 and 4 in the 2021-2030 period, there would also be significant and increasing annual investment required beyond 2030 to achieve these targets. Even then, it is unlikely that the targets could be achieved (based on current assumptions and pipeline) until the latter half of the subsequent decade at best.

Stakeholder consultations held in 2021 may conclude that changes to the assumptions are warranted.

The ongoing benefits of multistage vaccines and the most appropriate strategies for modelling their development pathways and associated costs will also be important to secure agreement on if we endeavour to paint a more accurate picture of the future of malaria vaccine R&D. The potential value of shorter-acting vaccines (e.g. for use in intensely seasonal transmission settings) would also need to be carefully considered and factored into the target setting and modelling.

In the case of diagnostics, VCPs, biologics, and endectocides, some of the assumptions relied on could benefit from significant further review and validation. For example, given the nascent state of biologics and endectocides R&D for malaria, we have had to rely on cost, duration and PTS assumptions that are currently difficult (if not impossible) to ground in real world experience. There is also less clear consensus on the prioritisation and classification of these two areas within the wider malaria R&D agenda, warranting review during future cost modelling exercises.

On the whole, the model itself could also benefit from some structural adjustments that better align research priorities and targets in certain product areas (e.g. resolving the TCP vs. TPP target-setting approach for malaria drugs) and that ensure the nuanced handling of different development and regulatory pathways are done with equal sophistication and accuracy across the various product areas (e.g. accounting for the need to demonstrate population efficacy for endectocides).

It is also worth noting that only a few costs associated with surveillance R&D (a major pillar of the GTS) are reflected explicitly in this particular model and the funding needed to advance R&D related to this area may require further consideration. The major needs could be categorised as follows:

- **Transmission intensity –** parasite complexity (genomics), exposure (genomics, serology), immunity (serology, others), vector surveillance.
- **Importation and case classification –** use of genomics in parasite strain mapping, understanding transmission chains.
- **Resistance/biological evasion –** drug and insecticide resistance markers, HRP2/3 gene deletions.
- **Cause of death –** minimally invasive autopsies, better verbal autopsy methods.
- **Digital solutions –** information systems, data integration, analysis and visualizations, civil and vital registrations.
- **Methodological advances –** measuring epidemiological transition, malaria burden, subnational tailoring of interventions, impact evaluations, understanding intervention effect sizes from routine data, non-randomized controlled trials for intervention impact assessment, measurement of transmission intensity, importation and case classification, resistance/biological evasion, cause of death, and digital solutions.

In this model, the development of high-throughput mosquito assays was included as a priority under the vector control product area, rather than under diagnostics, whereas the development of molecular assays for antimalarial drug resistance surveillance has been retained as a priority under diagnostics (as per the original projections). Both could alternatively be considered under a separate category of 'R&D for surveillance', along with some or all of the innovations described above.

This has been a priority-based exercise that assumes relatively perfect coordination across the various product areas and doesn't account very well for the globally disseminated nature of research or the potential for duplication and lack of harmonization inherent in that. This is one of the main arguments underpinning the use of the uncertainty multipliers in the model, but it is worth acknowledging that these are a fairly blunt tool addressing a wide range of difficult-to-quantify factors.

Concluding remarks

While the model outlines the malaria R&D funding needs, it doesn't address where the funding should come from or the optimal balance of public and private sector involvement in R&D financing. In general, significant gaps exist between current levels of investment in product development for poverty-related neglected diseases and what will be required to (a) move existing candidates all the way through the pipeline to launch, and (b) fill the many gaps in the current pipeline. Of course, attentions (and investments) in the global health sector remain dominated by COVID-19 and a global recession would undoubtedly have a cumulative impact on future ODA commitments (many tied to GNI) and available funding to address other health challenges. Strategic, innovative, and well-coordinated mechanisms for global health R&D funding (including malaria) are needed, more than ever, to close these widening gaps. Further analysis is warranted to pair malaria R&D funding needs with the appropriate resource mobilisation and financing strategies that will improve the prospects for advancing these critical malaria tools through the clinical development pipeline between now and 2030.

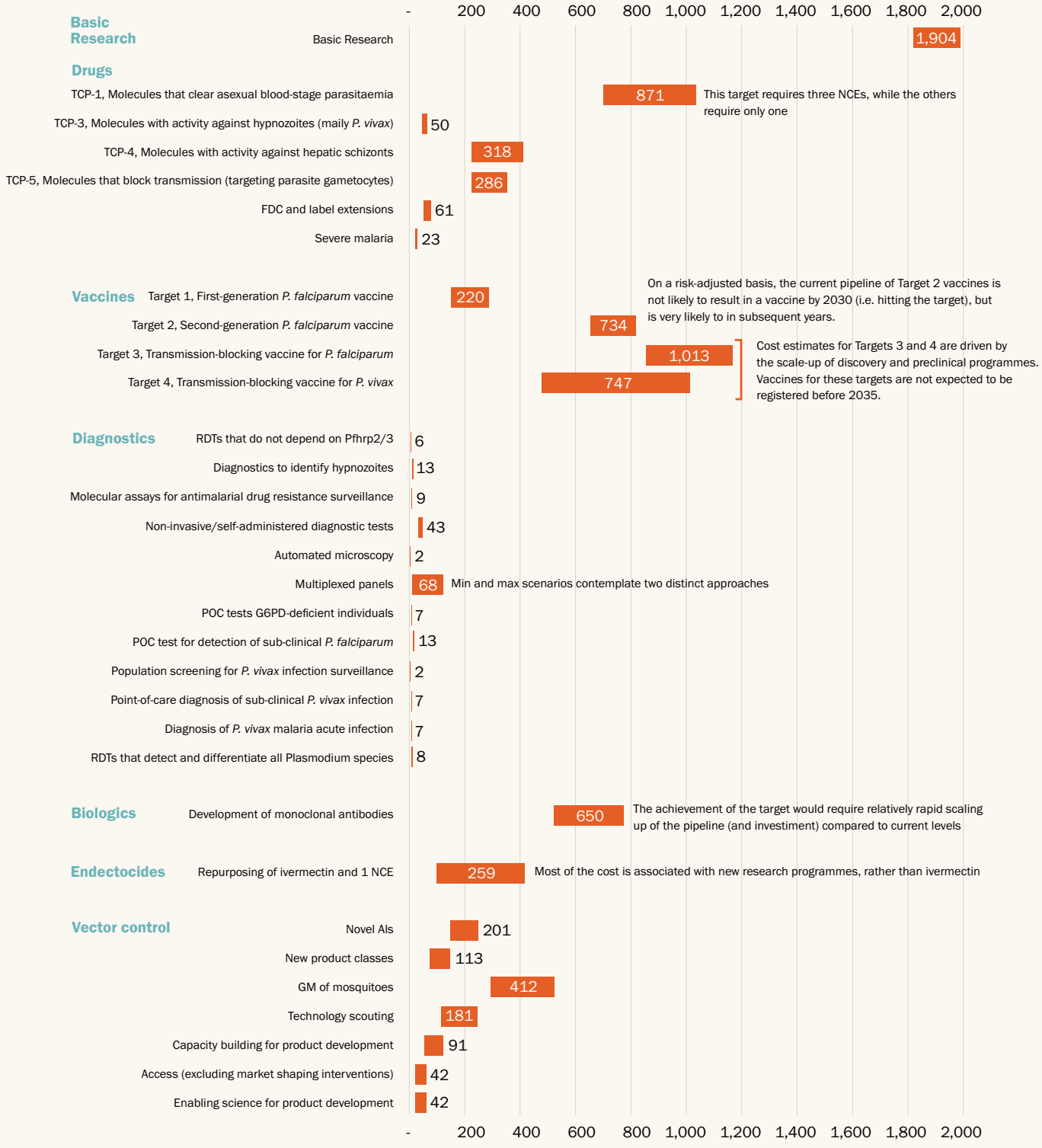
Annexes

Annexe I. Expert consultations

Name	Organisation	Area of speciality
Tim Wells	MMV	Drugs
Claude Oeuvray	Merck	Drugs
Lutz Hegemann	Novartis	Drugs
Ashley Birkett	PATH MVI	Vaccines
Chetan Chitnis	Institut Pasteur	Vaccines
Sabine Dittrich	FIND	Diagnostics
Xavier Ding	FIND	Diagnostics
Gonzalo Domingo	PATH Diagnostics Program	Diagnostics
Nick Hamon	IVCC	VCP
Mathias Mondy	IVCC	VCP
Stephanie James	Foundation for the National Institutes of Health	VCP
Michael Santos	Foundation for the National Institutes of Health	VCP
Regina Rabinovich	ISGlobal	Endectocides
Carlos Chaccour	ISGlobal	Endectocides

Annexe II. Funding requirement estimates

Figure 15: Required funding (midpoint and range) for each target



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