

FIND 

Because diagnosis matters

**STRATEGY
FOR MALARIA**

2015-2020

ABOUT FIND

FIND was founded in 2003 to bridge existing development gaps for essential diagnostics by initiating and coordinating research and development (R&D) projects in collaboration with the international research community, the public sector and the *in vitro* diagnostics industry. Today, FIND is a leading partner across the value chain of diagnostics development and delivery. We have programmes in tuberculosis and acute febrile respiratory infections, malaria and acute febrile syndrome, hepatitis C and neglected

tropical diseases. We also have mini-portfolios in areas affecting reproductive and child health: HIV; sexually transmitted infections; and infections and nutritional deficiencies in children less than five years of age. At FIND, we envision a world where diagnostics guide the way to health for all people. We aim to turn complex diagnostic challenges into simple solutions to transform lives and overcome diseases of poverty. To do this we focus on four strategic goals throughout all the disease areas in which we work:

■ Catalyse development

Identify needed diagnostic solutions and remove barriers to their development

■ Guide use & policy

Lead products through the clinical trials pathway to global policy on use and market entry

■ Accelerate access

Support uptake and appropriate use of diagnostics to achieve health impact

■ Shape the agenda

Improve understanding of the value of diagnostics and strengthen commitment to their funding and use

FIND's Vision

A world where diagnosis guides the way to health for all people

FIND's Mission

Turning complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives

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ABBREVIATIONS

| | |
|----------------|---|
| BTD | Blood transfer device |
| G6PD | Glucose-6-phosphate dehydrogenase |
| IPTp | Intermittent preventive treatment in pregnancy |
| ISTp | Intermittent screening and treatment in pregnancy |
| NAAT | Nucleic acid amplification test |
| PCR | Polymerase chain reaction |
| POC | Point-of-care |
| QA | Quality assurance |
| R&D | Research and development |
| RDT | Rapid diagnostic test |
| WHO | World Health Organization |

ABOUT MALARIA

Malaria is one of the four most burdensome infectious diseases globally and the fifth highest cause of child mortality. In 2013, there were an estimated 198 million cases and 584,000 deaths due to malaria. Despite these relatively large figures, remarkable progress has been made in malaria control during the last decade. According to the 2014 World Malaria Report, the number of malaria infections has dropped 26% since the year 2000, 55 out of 106 endemic countries are on track to meet the global target of reducing malaria incidence by 75% of 2000 levels by 2015, and 19 countries are already in pre-elimination or elimination phases. Sustaining these gains and accelerating actions toward malaria elimination requires improved access to appropriate individual diagnosis as well as effective surveillance tools.

The cornerstone of FIND's work on malaria has been the development and implementation of a global programme for the evaluation of rapid diagnostic tests (RDTs). Through this quality assurance (QA) programme, essential information is now available to guide RDT procurement and to assure performance of individual RDT lots before use in the field. The availability of high quality RDTs has significantly improved and in 2013, for the first time ever, the total number of RDTs procured exceeded the number of artemisinin-based combination therapies (ACTs) distributed in the WHO African Region. While access to appropriate diagnosis and treatment is increasing, it is estimated that only 62% of patients with suspected malaria received a diagnostic test in 2013. An important proportion of febrile patients in malaria-endemic countries seek care in the private sector where RDTs are unavailable or of substandard quality. There is, therefore, an important need for mechanisms to increase access to high quality RDTs in both the public and private health sectors in malaria-endemic countries.

While efforts continue to eliminate the most deadly form of malaria, caused by *Plasmodium falciparum*, detecting and treating malaria due to other *Plasmodium* species must also improve. Accordingly, better tools to detect and treat reservoirs of *P. vivax* parasites are urgently needed to eliminate this second-

most-important type of malaria. Accurate testing and treatment should be rationally implemented to enable radical cure of *P. vivax* through elimination of its dormant liver form, the hypnozoite, to avoid relapses and stop transmission. Furthermore, successes in malaria elimination are greatly dependent on the efficacy of antimalarial drugs. In response to the recent emergence of artemisinin resistance and to help combat any future resistance to other antimalarial drugs, new and effective surveillance tools to detect and rapidly contain it are of utmost importance. Active population screening to detect and treat not only clinical cases but also asymptomatic infections is required to stop transmission. Diagnostic solutions at different levels of the health system must be implemented to accelerate malaria elimination – highly sensitive RDTs to detect sub-microscopic parasites densities in blood are essential in remote areas, while high throughput molecular methods are required at a centralized level for disease and antimalarial resistance surveillance.

From 2015 to 2020, FIND will continue to support the Global Malaria Action Plan and WHO targets to bring global and national mortality near zero and support countries currently in the pre-elimination stage to achieve elimination. FIND also supports the long-term global goal of malaria eradication by reducing the global incidence of malaria to zero. For the second time in history, the world is actively fighting for malaria elimination. As progress is made toward this potentially historic achievement, our ability to accurately identify the remaining malaria infections with new and effective diagnostic tools is clearly a prerequisite for success. As malaria dwindles, new tools will help to keep antimalarial interventions focused and effective, and will enable malaria patients to be correctly treated in this rapidly changing context. Across all activities, collaborating with partners will be essential. We will continue working with academia, industry, national malaria control programmes, other international organizations, implementation agencies and global procurement agencies to reach our objectives and advocate for the prioritization of better malaria diagnostics.

PAST AND CURRENT ACTIVITIES

Malaria has been one of FIND's three core disease programmes since 2007. Our focus on this disease has evolved from primarily development and implementation of QA systems for RDTs to

strategies to maximize the impact of RDTs and develop new, much needed tools. The main achievements of the malaria programme so far include:

Supporting the development of innovative tools

FIND led the delivery of the loop-mediated DNA isothermal amplification (LAMP) kit for malaria, a field-stable, highly sensitive nucleic acid detection test that allows PCR-level malaria diagnosis. This kit was brought to the market in 2012 and has been introduced in nine low-endemic countries to detect asymptomatic infections and guide treatment to support elimination. A second-generation test with high throughput for population screening has completed development and is being tested

in the field in 2015. FIND also developed a blood transfer device (BTD) for use with malaria RDTs that overcomes issues of ease of use, volume accuracy and blood safety, improving upon other existing designs. This BTD has been widely adopted and in 2014 reached more than 150 million patients with suspected malaria around the world. The design of this tool has inspired the development of a similar higher-volume BTD for HIV and sleeping sickness RDTs.

Forging the path to uptake

In collaboration with the WHO and several partners in endemic and non-endemic countries, FIND has developed and implemented a global malaria RDT evaluation programme to guide public sector procurement of malaria RDTs (product testing), and to ensure the quality and safety of product batches before they are distributed in the field (lot testing). Since the start of the programme in 2007, there has

been a substantial increase in the quality of tests being procured. Among malaria RDTs submitted to lot testing, 99.5% met WHO procurement and quality standards in 2014 compared to 71.2% in 2007. FIND and partners are currently establishing mechanisms to ensure the long-term sustainability of the programme and the implementation of good quality RDTs in the private sector.

Guiding proper use

With our partners and in multiple languages, we published job aids, training materials and instructions for transport and storage of RDTs that are improving the quality of their use in remote areas. In 2013, FIND released the first complete

implementation manual of its kind to guide country programmes in the introduction and use of malaria RDTs. Work is now ongoing to adapt those manuals and tools to support the implementation of RDTs in the private health sector.



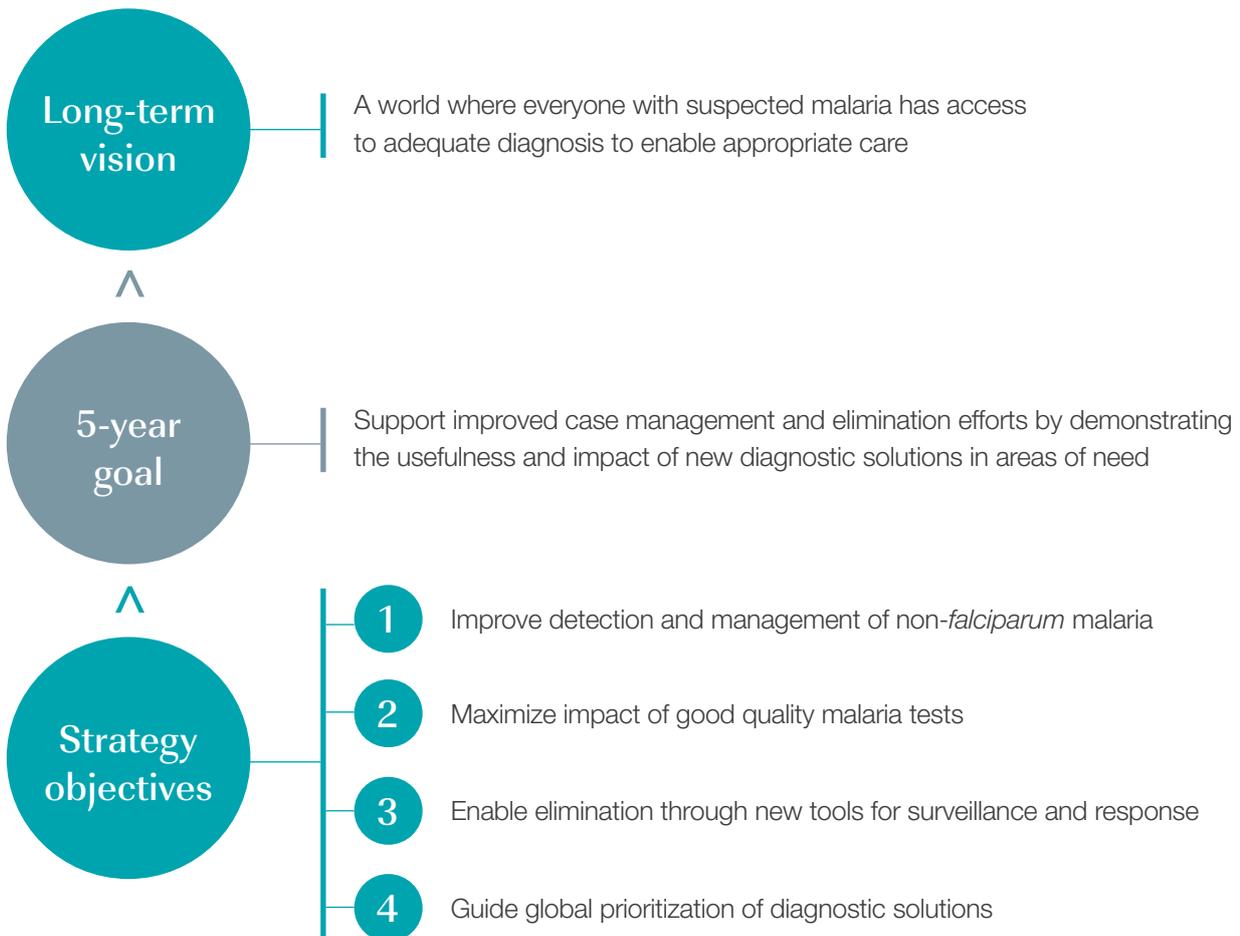
IMPROVING CASE MANAGEMENT
AND ACCELERATING MALARIA
ELIMINATION WILL ONLY BE
ACHIEVED THROUGH THE SCALE-
UP OF INNOVATIVE, HIGH-QUALITY
DIAGNOSTIC SOLUTIONS WORLDWIDE.

GOALS AND OBJECTIVES OF THE FIND MALARIA PROGRAMME

The vision of FIND’s malaria programme is a world where everyone with suspected malaria has access to adequate diagnosis to enable appropriate care. Improving case management and accelerating malaria elimination will only be achieved through the scale-up of innovative, high-quality diagnostic solutions worldwide. We will achieve our goals by focusing on the following core objectives:

- Improve detection and management of malaria cases due to non-*falciparum* infections
- Maximize impact of existing and new, good quality tests
- Enable malaria elimination through development of new tools for surveillance and response
- Guide global prioritization of diagnostic solutions for malaria

Addressing challenges to meet global goals of malaria programme



GLOBAL DIAGNOSTIC NEEDS AND CURRENT LANDSCAPE

In order to achieve the objectives of FIND's malaria strategy and to enable global goals, FIND has identified a variety of needs ranging from development to delivery of diagnostic solutions. Regarding development needs, robust, simple and easy-to-use tests are required to improve case management, while high throughput

and simple solutions should be standardized and implemented for surveillance of malaria cases and antimalarial resistance. Regarding delivery, standard reference materials and QA systems for existing and new diagnostic tools are necessary at all levels of the public and private health sectors.

Improving case management

Prompt detection and adequate treatment are the first steps in controlling transmission and accelerating malaria elimination. Better RDTs to detect non-*falciparum* species and more sensitive tools for malaria during pregnancy are required. Access to appropriate, high-quality malaria diagnosis in both the public and the private health sector must be increased.

Better diagnostics for non-*falciparum* malaria:

Malaria is a parasitic disease due to the infection of humans by five different *Plasmodium* species. The most deadly form of the disease is the one produced by *P. falciparum*, while the chronic and persisting form of the disease is produced by *P. vivax* parasites. Around 2.85 billion people around the world are at risk of infection with *P. vivax* parasites, 57% of them living in areas of unstable transmission. In countries where both *P. falciparum* and *P. vivax* parasites are transmitted, the incidence of *P. falciparum* is decreasing faster than that of *P. vivax*, in large part due to the biological characteristics of these parasites. This is illustrated by the fact that *P. vivax* parasites are more prevalent in countries that are in pre-elimination and elimination phases. Infections by *P. vivax* parasites are characterized by inducing

symptoms at lower parasite densities in blood than those by *P. falciparum*; by producing gametocytes, the form that is transmitted to mosquitoes, earlier in the infection; and by generating hypnozoites, a dormant form of the parasites that can persist, undetectable, in the liver for years or even decades.

While specific detection of low amounts of *P. vivax* parasites in blood by microscopy is challenging, there are few RDTs in the market that can detect this parasite species. Only 21% (28/133) of all RDTs in the market are able to detect *P. vivax* parasites and only 12 of them fulfil the WHO procurement criteria. Stability testing demonstrates that, contrary to *P. falciparum*-specific tests, the performance of *P. vivax*-specific RDTs is negatively affected by transport and storage at tropical conditions. Furthermore, there are currently no diagnostic tools available to detect reservoirs of hypnozoites, although they could indirectly be detected by the presence of parasites in blood in asymptomatic infections or by the presence of host biomarkers. All these characteristics, plus the fact that radical cure of *P. vivax* infections requires the use of drugs that could be toxic to people deficient in glucose-6-phosphate dehydrogenase (G6PD), highlight the urgent need for accurate, more sensitive and more stable diagnostic test for this form of malaria.

Diagnosing malaria during pregnancy:

Malaria during pregnancy has catastrophic effects, from anaemia and low birth weight in areas of high transmission to severe malaria and foetal death in areas of low transmission. The benefit of intermittent preventive treatment during pregnancy (IPTp) with sulphadoxine-pyrimethamine (SP) has been demonstrated and is currently recommended by the WHO. However, evidence of declining efficacy of IPTp is emerging due to the increase in parasite resistance to SP. Finding the next single-use, safe and well-tolerated drug for IPTp has proven difficult. Intermittent screening and treatment during pregnancy (ISTp) has been proposed as an alternative to IPTp. Testing for malaria infections during each antenatal visit will better guide the use of efficacious antimalarial treatment. This approach will be even more important and cost-effective in areas of low transmission where pregnant women are less exposed to the disease. Although the usefulness of RDTs to detect malaria parasites in pregnant women and predict placental malaria has been demonstrated, a considerable number of infections are still missed by RDTs when compared to nucleic acid amplification techniques (NAATs). More sensitive tests with levels of detection similar to NAATs but easier to use in

endemic settings will be needed to implement ISTp in areas of need.

Increasing access to malaria diagnosis in the private health sector:

According to the last WHO Global Malaria Report, it is estimated that around 40% of the population at risk seeks care in private health facilities, pharmacies and retail outlets where malaria diagnosis is either nonexistent or more expensive than treatment. In consequence, a large proportion of these febrile cases are empirically treated as malaria, leading to the overuse of antimalarial drugs and mistreatment of other potentially life-threatening febrile illnesses. Efforts from implementing organizations are currently underway to create a market for RDTs in the private health sector of endemic countries. While concerted work with health ministries and regulatory bodies is needed to harmonize disease policy and procurement, training tools and guidance on proper RDT use are also required. Integration with national QA systems and supervision of operator performance will also be needed to ensure access of patients to good quality RDTs in the private sector.

Maximizing impact of good quality tests

The need for up-to-date information on quality of diagnostics will continue to grow as the market expands with the addition of new products. The Malaria RDT Evaluation Programme developed by FIND in collaboration with WHO and other partners has demonstrated that global QA programmes for diagnostics can shift the market towards higher quality products and guide the use of better tests in endemic countries. However, such programmes should be managed sustainably with support from mainstream programme funds instead of relying on donor funds only. Endemic countries should also have the capacity to appropriately regulate

the use and control the quality of diagnostic tests. Sustainable systems are then needed to: i) evaluate performance of commercially available tests in an independent way to allow procurers and control programmes to select good quality products, ii) control the quality of individual lots before they are distributed in the field, iii) assess the quality of tests in the field and iv) have the necessary tools and processes to act appropriately if any quality problems arise. Standard protocols and reference materials must be implemented to ensure the quality of existing and new tests from manufacturer to the end user.

Enabling global malaria elimination and surveillance

Malaria elimination can only be achieved if all malaria infections are detected and promptly treated to stop transmission. More sensitive tools able to detect sub-patent infections are required in remote settings for active detection and at reference laboratories for surveillance. New tools that are needed include:

Detection of asymptomatic infections in remote settings

It has been demonstrated that asymptomatic infections contribute to the perennial transmission of malaria in endemic settings. While microscopy and RDTs are appropriate for case management, they miss more than 50% of asymptomatic infections when compared to NAATs. A highly sensitive test that would allow for the rapid detection and on-site treatment of all infections in remote settings, including asymptomatic cases, is required. One tool that would have a substantial impact is an improved RDT that can detect sub-microscopic infections, thereby identifying more infections and guiding rapid treatment to stop transmission.

Surveillance of malaria and antimalarial drug resistance

Multiple simplified NAATs such as LAMP have demonstrated superiority to microscopy and RDTs

in the detection of asymptomatic infections. The requirement of electricity and basic infrastructure confine their use to health facilities where reference testing for surveillance could be done. NAATs have been traditionally used for research in specialized institutions but their use in national reference laboratories is currently increasing. Standard reference materials and methods for QA schemes to demonstrate performance and harmonize data are required. Resistance to artemisinin, the primary drug used in current combination therapies for malaria, has been confirmed near the Cambodian-Thailand border, and global action has been launched to contain and halt its spread. The Global Plan for Artemisinin Resistance Containment from the WHO has prioritized increased monitoring and surveillance to evaluate the threat of artemisinin resistance. The development of simpler tools for antimalarial resistance surveillance will facilitate the implementation and quality control of standard methods at national reference laboratories. Simultaneously, to enable better management of country control and elimination programmes and capture the wealth of data being produced by diagnostic tests, improved country surveillance programmes must be implemented. Such programmes greatly benefit from the electronic processing of diagnostic and surveillance data through eHealth technologies. These have the potential to accelerate data collection, improve data quality and facilitate prompt reactions as part of surveillance and monitoring activities.

Guiding global prioritization of diagnostic solutions for malaria

In order to address identified needs and achieve malaria elimination, global commitment to the development and implementation of diagnostics has to be expanded. The value of diagnostics for malaria control and elimination must be demonstrated

through evidence and impact measurement. This will provide the foundation for global policy change and advocacy efforts to improve the visibility and increase the profile of diagnostics for malaria in global and regional fora.

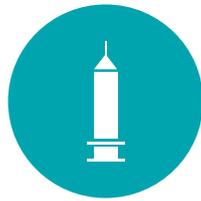
Diagnostic tools needed for malaria across the health care system



Community health worker



Health post



Health centre



District hospital



Reference centre

Better diagnostics for non-*falciparum* malaria

Diagnosing malaria during pregnancy

Increasing access to diagnosis in the private sector

Maximizing impact of good quality tests

Detection of asymptomatic infections for elimination

Surveillance of malaria and antimalarial drug resistance

e-Health and connectivity solutions

Addressing non-malaria fevers

As accurate diagnosis for malaria is introduced across malaria-endemic regions, it is becoming increasingly apparent that most fevers are due to other diseases. As malaria incidence declines, alternative causes of acute fever also need to be addressed. There are multiple diseases that present with symptoms similar to malaria, including pneumonia, typhoid fever and dengue. The use of good quality RDTs for malaria and the absence of rapid tests for other potential causes of fever are driving the overuse of antibiotics in RDT-negative febrile cases. While causes of acute fever are multiple and vary widely with geography, living conditions and occupational exposure, tools to guide use of antibiotics, supportive treatment and referral decisions should be validated and incorporated in improved algorithms for fever management.

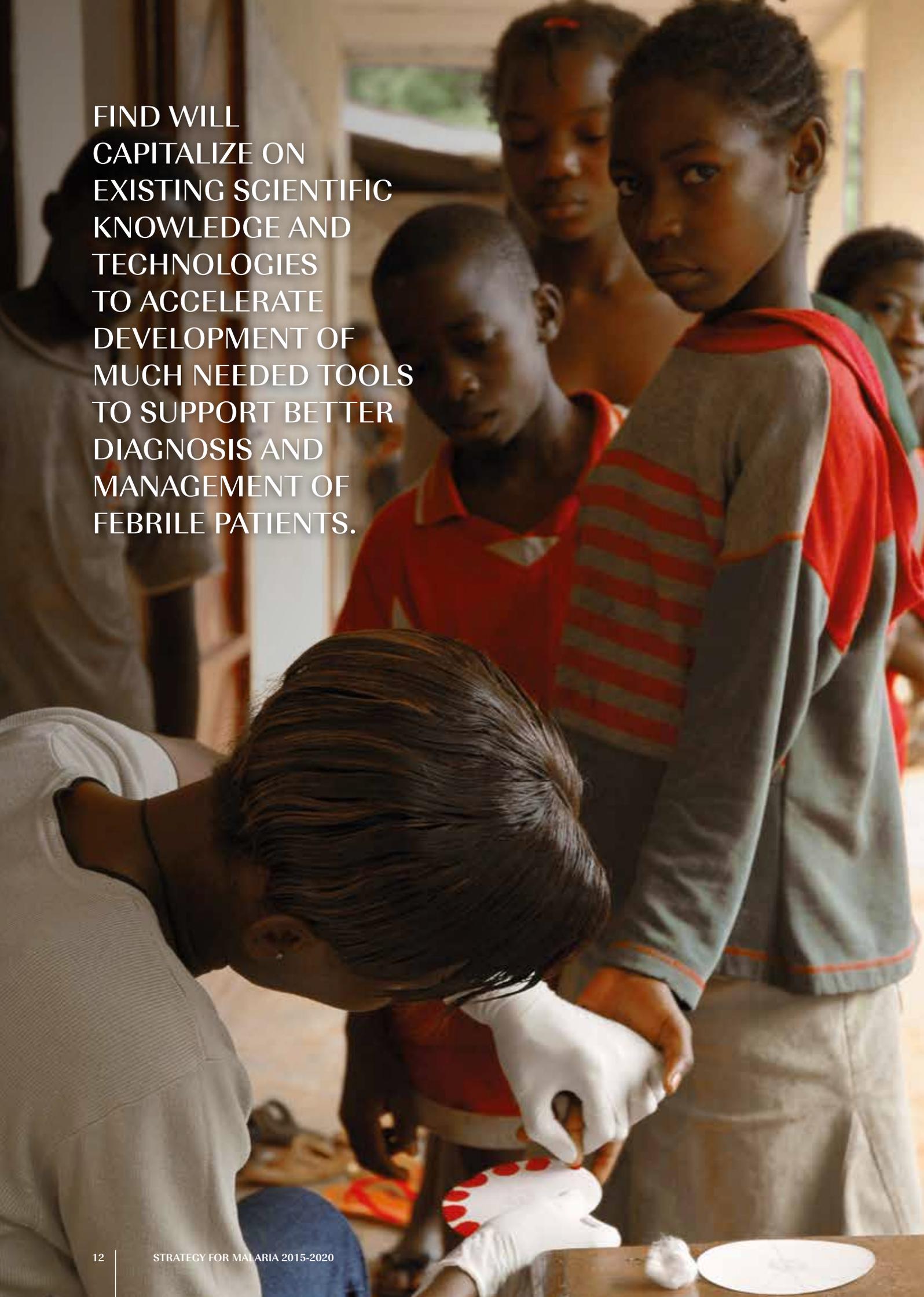
Bacterial versus non-bacterial infections: To improve management of acute fever, it is not always necessary to identify the exact cause of the illness. Some causes of fever are mild and self-limiting and are best managed by controlling temperature or providing basic care. However, other causes of fever require antibiotic treatment to avoid progress to severe disease. While some biomarkers such as procalcitonin and C reactive protein have been used to distinguish bacterial from non-bacterial infections, their performance is not optimal and their presence could be confounded by the presence of co-infections. New, more accurate biomarkers in appropriate point-of-care formats are required to guide the use of antibiotics in remote settings. Decreasing the indiscriminate use of antibiotics will contribute to control antimicrobial resistance by reducing the emergence of bacteria resistant to common valuable drugs.

Severity biomarkers: The causes of severe acute febrile illness are numerous and account for many preventable deaths in low-income countries, particularly in children. Prevention of severe illness and death relies on early detection and treatment. Tools to identify risk of severity would help health workers in the decision-making process to promptly refer patients to a higher level of the health system. Host biomarkers mostly related to the immune response to severe infections have been identified and are currently in use in clinics with access to sophisticated technologies. Easy-to-use and robust tools detecting severity biomarkers should be developed in order to improve clinical algorithms for adequate management of acute fever in low resource settings.

Detection of pathogens causing acute fever: Some well-established technologies are already in use in reference laboratories to identify the specific causes of acute infectious febrile diseases. *In vitro* culture combined with microscopy, ELISA tests and NAATs are currently used to identify viruses, bacteria and parasites, as well as antimicrobial resistance, in blood or other types of samples. Required infrastructure and complexity of these diagnostic tools limit their use to clinics and hospitals for treatment of critical patients. However, even at the hospital level, diagnostics that can distinguish many common causes of severe illness and death are unavailable in tropical and sub-tropical settings. Simplified and robust methods for the identification of common causes of fever and antimicrobial resistance, adapted to different levels of the health system, need to be developed. In addition to guiding individual case management, they will provide prompt information on the incidence and geographical spread of pathogens to plan and target preventive actions.

Supporting better diagnosis and management of febrile patients is a common need in all disease programmes at FIND. We will work across disease programmes to leverage existing expertise, biobanks, trial sites and overall capacity in order to accelerate the development and implementation of diagnostics for acute febrile syndrome.

FIND WILL
CAPITALIZE ON
EXISTING SCIENTIFIC
KNOWLEDGE AND
TECHNOLOGIES
TO ACCELERATE
DEVELOPMENT OF
MUCH NEEDED TOOLS
TO SUPPORT BETTER
DIAGNOSIS AND
MANAGEMENT OF
FEBRILE PATIENTS.



FIND'S MANDATE IN MALARIA FOR 2015 TO 2020

Defining our priorities

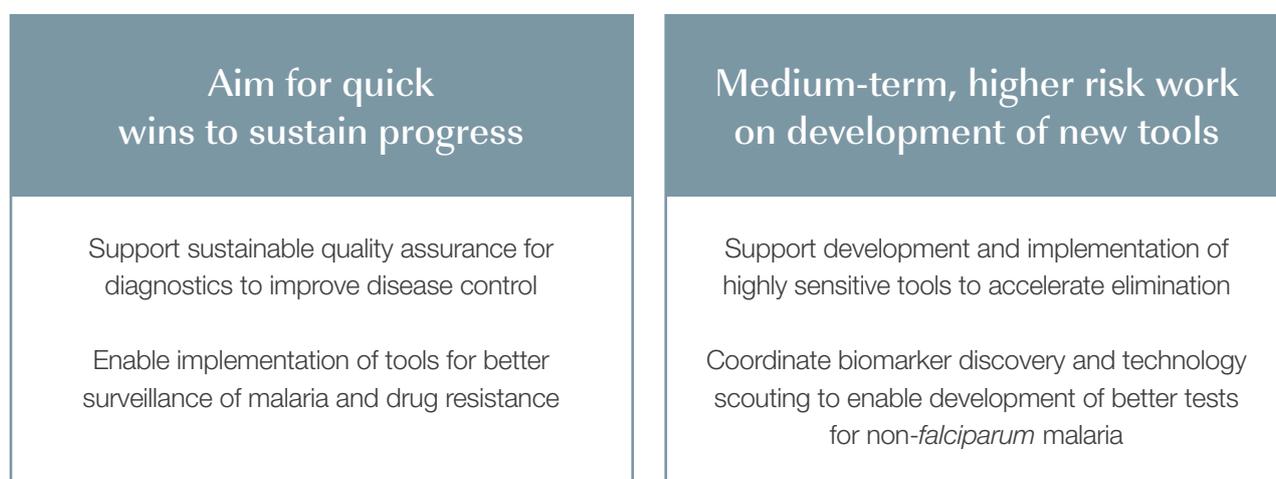
The range of potential interventions in malaria is broad and FIND has defined its priorities in this area of work for the next five years based on two specific criteria: the expected impact of diagnostic solutions on individuals and overall public health; and the likelihood of FIND's success given technical

feasibility, fit with FIND capabilities and availability of funding. We will capitalize on existing scientific knowledge and technologies to accelerate development of new and much needed diagnostic tools and build upon existing projects to support scale-up.

A two-pronged approach to prioritization of activities in malaria

Given that tools to address malaria elimination are in the early stages of development and that implementation strategies need to be scaled up and sustained...

...we will take a two-pronged approach to prioritization



In the development of new tools, FIND's top priorities are: **highly sensitive point-of-care diagnostics** for detection of malaria during pregnancy and to accelerate malaria elimination, and **improved tests for *P. vivax* malaria** to detect and guide appropriate radical cure of this type of the disease. FIND will generate evidence to support policy development on the use of recently developed and new tools to meet these needs.

FIND's work has demonstrated the positive impact of implementing **QA programmes**, from manufacture to end user, on increased access to good quality diagnostic tests. We will continue working in this area to create mechanisms to implement sustainable RDT QA programmes in the public and private health sectors in malaria-endemic countries, at regional and national levels, including methods and tools for quality control at the end user level. Simultaneously, FIND will support the establishment of QA programmes for molecular

diagnostics and laboratory methods for detection of antimalarial resistance. This will be an important component for the implementation of appropriate **surveillance of malaria and antimalarial drug resistance**. FIND's work in this area will be focused on the development and WHO endorsement of appropriate standard materials, supporting laboratory strengthening and implementation of improved data collection tools. Across all activities, we will place a high priority on ensuring that tests are compatible and used in combination with **eHealth solutions** and are accompanied by supporting connectivity tools to increase their benefit not only for patient management but also for appropriate use of results at higher levels. These eHealth solutions will allow for safe, efficient and appropriate collection, storage and transmission of valuable diagnostic data, with potential impact beyond the care of the individual patient to include health systems management and definition of appropriate public health interventions.

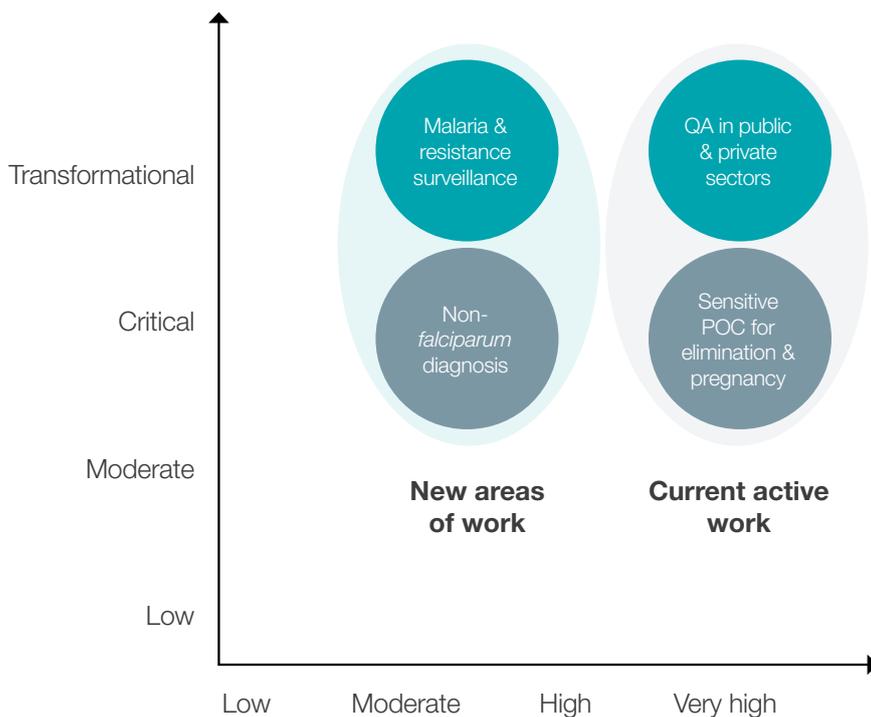
Prioritization of needs to be addressed with development of new tools and supporting implementation

Impact

- Public health and individual impact

Key

- FIND supports development
- FIND supports implementation



Likelihood of FIND success

- Technical feasibility
- Availability of funding
- Fit with FIND capabilities

Enabling interventions

FIND will support objectives for malaria through a set of enabling activities across our organizational pillars. These activities include:

Catalyse development:

FIND will establish and maintain openly available specimen and strain banks to support the development of new tests. We will also conduct biomarker landscaping and technology scouting to identify potential solutions for needs described in detailed target product profiles (TPPs).

Guide use and policy:

We will conduct the required operational research, evaluation and demonstration studies to determine if and how the use of existing and new tools can be improved and to support accompanying policy guidance with evidence data.

Accelerate access:

FIND will enable in-country development and execution of national guidelines and plans for implementation of new and existing tools based on global best practices. We will support improved global and local QA of current and new diagnostic tests to stimulate development and manufacturing of better quality products, as well as ensure that only good quality and properly used tests reach patients. Interventions will be accompanied by eHealth solutions for improved data collection and management.

Shape the agenda:

We will measure and communicate the impact of improved diagnostics based on randomized control trials and cost-effectiveness studies. Working with procurement agencies and other stakeholders, we will provide strong evidence to guide decisions and shape the market for new malaria diagnostics.

FIND'S IMPACT IN THE FIGHT AGAINST MALARIA

Expected impact and 2020 targets

| Intervention | Direct indicators by 2020 | Patient-important outcomes | Population-level indicators |
|---|--|--|---|
| Support development of highly sensitive POC test for detection and treatment of asymptomatic malaria infections | Highly sensitive POC test being implemented in 5 low-to middle-income countries (LMICs) | Reduction of risk of relapse and reinfection | <ul style="list-style-type: none"> Reduction of disease incidence Accelerate elimination of malaria |
| Support implementation of laboratory methods for surveillance of malaria and antimalarial resistance | Quality assured laboratory methods implemented in 15 pre-elimination LMICs | | |
| Support development of improved tests for control and elimination of malaria due to <i>P. vivax</i> parasites | <ul style="list-style-type: none"> Quality-assessed molecular tests for <i>P. vivax</i> in demonstration studies in 5 LMICs At least 2 new improved RDTs developed and in field evaluation Serology biomarkers identified and tests for detection of recent and persistent infection in development | | |
| Sustainable QA for malaria RDTs | <ul style="list-style-type: none"> User-fee supported system is in place and fully rolled out In-country lot testing of RDTs is implemented in at least 20 LMICs Positive control wells (PCWs) for RDTs are in use in at least 20 LMICs | Appropriate diagnosis of malaria | Targeted use of antimalarial treatment |

| Intervention | Direct indicators by 2020 | Patient-important outcomes | Population-level indicators |
|--|---|--|--|
| Support implementation of RDTs in the private health sector | Quality assured RDTs are in use in the private sector in at least 10 LMICs | Appropriate diagnosis of malaria | Targeted use of antimalarial treatment |
| Support implementation of eHealth solutions for QA of diagnostics and disease surveillance | eHealth tools are adopted and in use in at least 10 LMICs | Reduction in time to diagnosis and treatment | <ul style="list-style-type: none"> Improved real-time available data Decrease in time to response to focal needs |
| Measure and communicate impact of diagnostic solutions for malaria | At least 3 cost-effectiveness studies of diagnostic solutions for malaria control and elimination | Access to appropriate diagnosis | Reduction in malaria incidence |

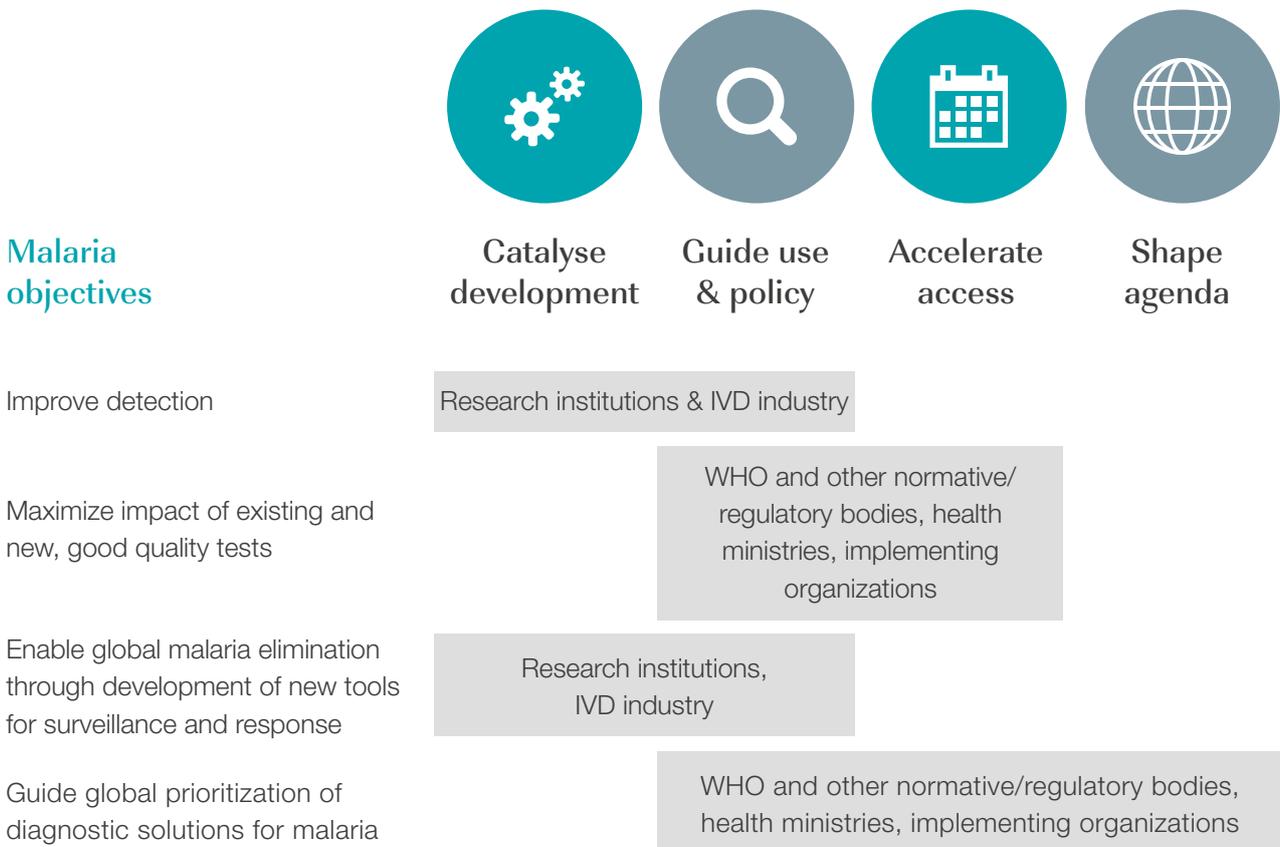
EXPANDING OUR PARTNERSHIPS

Across all of FIND’s activities, our partnerships with academia and industry are essential. We will strive to maintain and strengthen the longstanding relationships we have established with partners in development, operational research, QA and in-country implementation. The WHO Global Malaria Programme and its regional offices will remain some of our most important partners. We will also foster new collaborations to support other elements of our work. For example, to develop a highly sensitive RDT for malaria, we will work in close partnership with PATH, the Bill and Melinda Gates Foundation

and a range of manufacturers. Given the inherently multi-disease nature of the work on fever, our efforts in this domain will support new cross-disease partnerships, which will involve FIND’s technical teams across all diseases.

To support implementation activities, roll-out of new tools and the handover of QA to countries, we will foster strong relationships with national ministries of health, malaria control programmes and regulatory bodies. We will also strengthen our affiliations with implementing agencies in

Expanding our partnerships across the value chain



countries doing work on malaria diagnostics, such as PSI, Malaria Consortium, the President's Initiative on Malaria/USAID and the Clinton Health Access Initiative. Similarly, as we continue to encourage prioritization of diagnostics for malaria and investment in quality-assured products, we will partner with global agencies (e.g., the Global Fund and the WHO Prequalification of Diagnostics Department) and country policy makers. Additionally,

we will explore synergies to work with other product development partnerships dedicated to vaccine and drug development (e.g. Malaria Vaccine Initiative, Medicines for Malaria Venture) to leverage experience and capacity in specimen collection, clinical trials and impact measurement. Lastly, we will also work closely with nongovernmental organizations and advocacy groups to disseminate information on shaping the diagnostics agenda.

THE NEXT STEPS

Having the right diagnostic solutions for malaria in place is essential for achieving global goals in reducing childhood mortality, improving public health in low-resource communities and eliminating malaria. Correct diagnosis enables us to collect information that guides decision-making and lowers the overall costs of other interventions, reducing wastage and incorrect treatment. Diagnostics development is a relatively low-cost, high-impact investment that can deliver measurable results in a relatively short time, while greatly increasing the value of investments in other interventions.

The international health community has made much progress in the fight against malaria over the past decade, which has been possible partially due to committed funding to research and development (R&D) for infectious diseases in developing countries. In order to allow diagnostic solutions to play their pivotal role in enabling malaria elimination and to adequately respond to other causes of fever, greater resources must be committed to their development. With malaria diagnostics receiving only 2% of total malaria R&D funding in 2013, it remains a significantly underfunded field, and the non-malarial causes of acute fever are truly neglected. As long as funding remains well below the levels needed for the tools required for successful advancement

in the field, particularly as countries move towards elimination, this will remain one of the biggest challenges in overcoming malaria worldwide.

In its 2013 report on malaria R&D funding, PolicyCures recommended an immediate doubling of funding for malaria diagnosis to around US\$ 34 million per year to meet elimination targets and goals. As effective diagnostics are needed to support the development and implementation of other tools for malaria control, a lag in diagnostics development and implementation will further impede the impact of other investments.

Meeting targets for malaria control and elimination will require increased political and funding commitments to diagnostics R&D. FIND is committed to meeting global targets of reducing malaria incidence to zero and empowering local stakeholders to play a larger role in regulation, QA and efficient implementation of malaria diagnostics. Increased global investments and cooperation are key to fighting malaria and supporting sustainable progress in low-income countries. FIND will continue to play a leading role in fostering partnerships and collaborations to encourage national ownership of malaria elimination and increase autonomy in low-income countries.

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