



The WHO

Global Observatory on Health Research and Development (R&D)

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What is the Global Observatory on Health R&D?



- The Global Observatory on Health R&D (‘the Observatory’) is a **centralized and comprehensive source of information and analyses** on global health R&D activities for human diseases.
- Observatory aim: to **map and synthesize** health R&D activities to enable evidence-based decisions on **R&D priorities** by the newly established **WHO Expert Committee on health R&D** and other global stakeholders.
- **Target users:** Governments, policy-makers, funders, researchers.
- **URL:** www.who.int/research-observatory/en/

Scope

- Primary scope (as outlined in World Health Assembly resolution **WHA69.23**):
 - **type II and type III diseases** (i.e. diseases incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries, and diseases that are overwhelmingly or exclusively incident in developing countries respectively);
 - the specific R&D needs of developing countries in relation to **type I diseases** (i.e. diseases incident in both rich and poor countries, with large numbers of vulnerable populations in each);
 - potential areas where **market failure** exist;
 - **antimicrobial resistance** and emerging infectious diseases likely to cause **major epidemics**.
- As more data and resources become available, the Observatory will expand the diseases and types of health research it covers.

Status: New expert committee on health R&D

- Work ongoing to:
 - Select and **appoint experts** to a panel (formal process)
 - Produce **comprehensive analysis of malaria R&D** needs and priorities (will serve as prototype for future work)
 - **Develop the methods** for the priority setting process
 - **Plan for the first meeting** of the expert committee and any consultative processes that may be required beforehand

An approach to identify priority challenges and R&D priorities for malaria

WORK IN PROGRESS - FOR INPUT



**World Health
Organization**



R&D priorities for malaria

- Malaria – a path-finder for disease-specific R&D prioritisation
- WHO identified the Malaria Eradication Scientific Alliance (MESA) to conduct the analyses
 - Builds on a broad consultative exercise to identify R&D Priorities for malaria eradication – MalERA

Consultations on basic science, drugs, vaccines, vector control, diagnostics, health systems & operational research, M&E and surveillance, modelling

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Malaria Eradication Research Agenda

PLoS Med 2011; 8(1): e1000406

MESA Refresh

- MESA currently updating the R&D agenda – further extensive consultation www.malariaeradication.org/malera-refresh
- Asked to expand the prioritisation exercise
 - Consider R&D for control as well as eradication
 - Expand to consider operational research / implementation science



1663 VIEWS

Basic science and enabling technologies



1619 VIEWS

Insecticide and drug resistance



1757 VIEWS

Characterizing the reservoir and measuring transmission



2019 VIEWS

Tools for elimination



1931 VIEWS

Combination interventions and modelling



1435 VIEWS

Health systems and policy research



Overview

Aim

- **Identify challenges and opportunities for future impact**
 - Based on analyses of potentially critical areas of basic, product development and operational research
- Create a **supportive environment for prioritization of challenges and research** by the WHO/GMP
- **Define a ‘baseline’ for monitoring and evaluation of priorities and progress** through the WHO Global Observatory for Health R&D

Proposal

- Draft a report for initial consultation with GMP & MPAC
- Incorporate MESA Track & other databases of products in development, and include examples of key basic research and delivery science solutions

METHODOLOGY

1. Challenges identified

- Impact on malaria cases/ mortality/ elimination
 - Cannot be addressed using current products/strategies
- Sources: malERA Refresh, WHO GTS, GMP, WHO guidance and policies

2. Challenges mapped to Problems

- Problems that need to be addressed
- Sources: malERA Refresh, WHO GTS, GMP, Literature search

3. Potential product solutions identified

- What kinds of solutions could address the problems?
- Sources: malERA Refresh, Literature search

4. Pull together the global pipeline of ongoing projects

Sources: VCAG, IVCC, WHO, FIND, PATH, UNITAID, MVI, Literature search, others tbd

5. Map the pipeline onto potential product solutions

6. Identify, priorities, gaps and opportunities

- Priorities for accelerating R&D
- Gaps where innovation is needed
- Opportunities for potentially disruptive technologies

Development of R&D priorities: CHALLENGES

1. CHALLENGES FOR MALARIA WERE IDENTIFIED

Optimizing and managing adaptations to tools and strategies

Regions with high transmission intensity

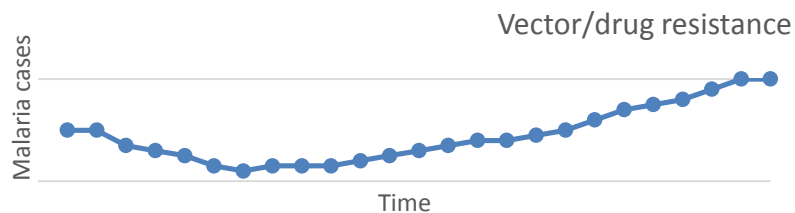
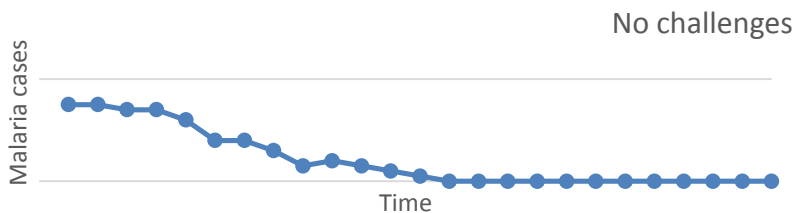
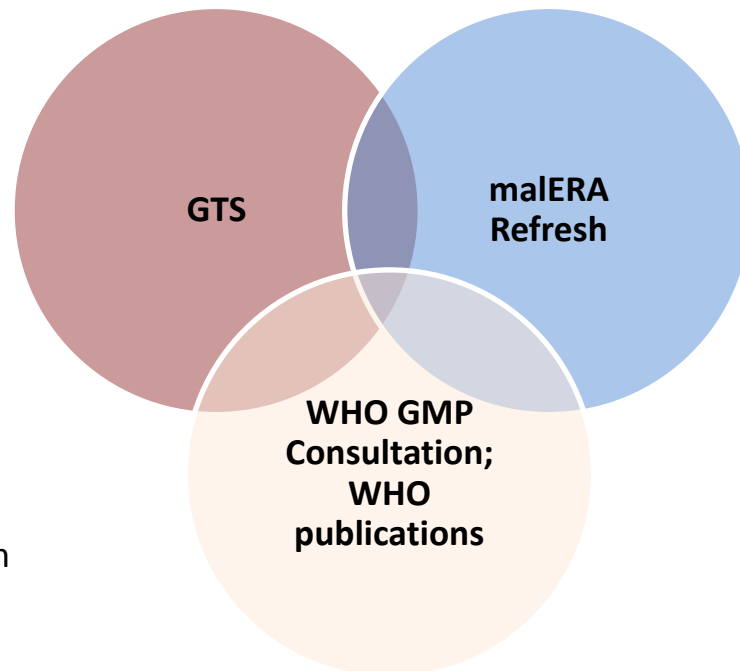
Residual transmission and accelerating elimination

Achieving universal access (including the “5th child”)

Addressing *P. vivax* and non-falciparum species

Achieving, documenting and maintaining elimination

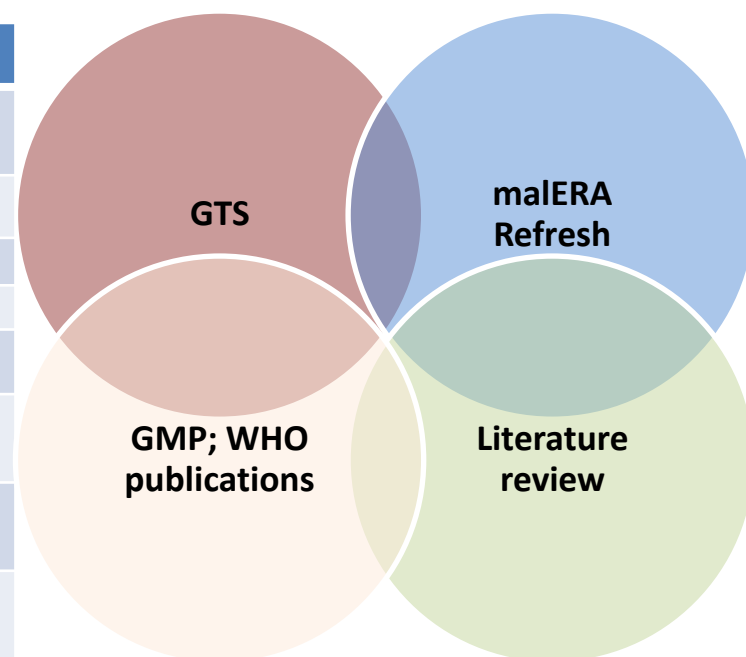
Assumptions: No silver bullet; Multiple products and strategies can potentially address challenges; innovation required to solve each challenge



Development of R&D priorities: PROBLEMS

2. Problems were mapped to challenges

| | |
|--|---|
| Optimizing and managing adaptations to tools and strategies | Vector resistance to insecticides (biochemical and behavioral) |
| | Parasite resistance to drugs |
| | Selection gene-deleted parasites |
| Regions with high transmission intensity | Extensive vector populations |
| | High rates of human to vector transmission |
| Residual transmission and accelerating elimination | Outdoor/daytime biting & zoophagy (including <i>P. vivax</i> vectors) |
| | Quantifying and targeting the transmission reservoir |
| Achieving universal access (including the "5th child") | Infrequent contact for prevention and treatment and failure of surveillance |
| Addressing <i>P. vivax</i> and non-falciparum species | Differential diagnosis of <i>Plasmodium</i> spp. |
| | Identifying and targeting hypnozoites and the transmission reservoir |
| Achieving, documenting and maintaining elimination | Rapid identification of importation, preventing and containing outbreaks |



- **QUESTION 1: DO THE CHALLENGES AND PROBLEMS IDENTIFY THE TOP ISSUES THAT COULD DRIVE THE RESEARCH AGENDA?**

3. Mapping potential product classes to challenges (under development)

| Product class | Potential product solution | Challenges | | | | | | Proven |
|----------------|--|------------|---|---|---|---|---|--------|
| | | 1 | 2 | 3 | 4 | 5 | 6 | |
| Vector control | • New insecticide classes used in combination in extended duration LLINs and IRS | ■ | ■ | ■ | ■ | ■ | ■ | |
| | • Novel vector control tools | ■ | ■ | ■ | ■ | ■ | ■ | |
| | • Genetic approaches to vector control | ■ | ■ | ■ | ■ | ■ | ■ | |
| Diagnostics | • Highly sensitive POC diagnostics for identifying low-density, asymptomatic infection | | | ■ | | | ■ | |
| | • Highly sensitive POC diagnostics for identifying low-density, asymptomatic <i>P. vivax</i> infection | | | ■ | | ■ | ■ | |
| | • RDTs that detect and differentiate all <i>Plasmodium</i> species | | | | | ■ | | |
| | • Sensitive and specific POC diagnostics for <i>P. vivax</i> | | | | | ■ | | |
| | • Diagnostics to identify high-density, symptomatic infection | | | | | ■ | | |
| | • Affordable, simple and accurate | | | | | ■ | | |
| | • Infectivity/gametocyte detection | | | ■ | | | | |
| | • Non-invasive diagnostic tools | | | ■ | ■ | | ■ | |
| | • Stable, valid, specific and sensitive | ■ | | | | | | |
| | • Multiplexed POC tests of multiple species | | | | ■ | | ■ | |
| | • POC diagnostics to identify high-density, symptomatic infection | ■ | | | | | ■ | |
| | • POC/health system falsification | ■ | | | | | ■ | |
| Drugs | • High-throughput mosquito feeding assays | ■ | | ■ | | | ■ | |
| | • SERCaP | ■ | | ■ | ■ | | ■ | |
| | • New drug classes used in combination | ■ | | | | | ■ | |
| Vaccines | • Novel drugs for severe malaria | ■ | | | | | ■ | |
| | • Novel vaccines for severe malaria | | | | | | | |
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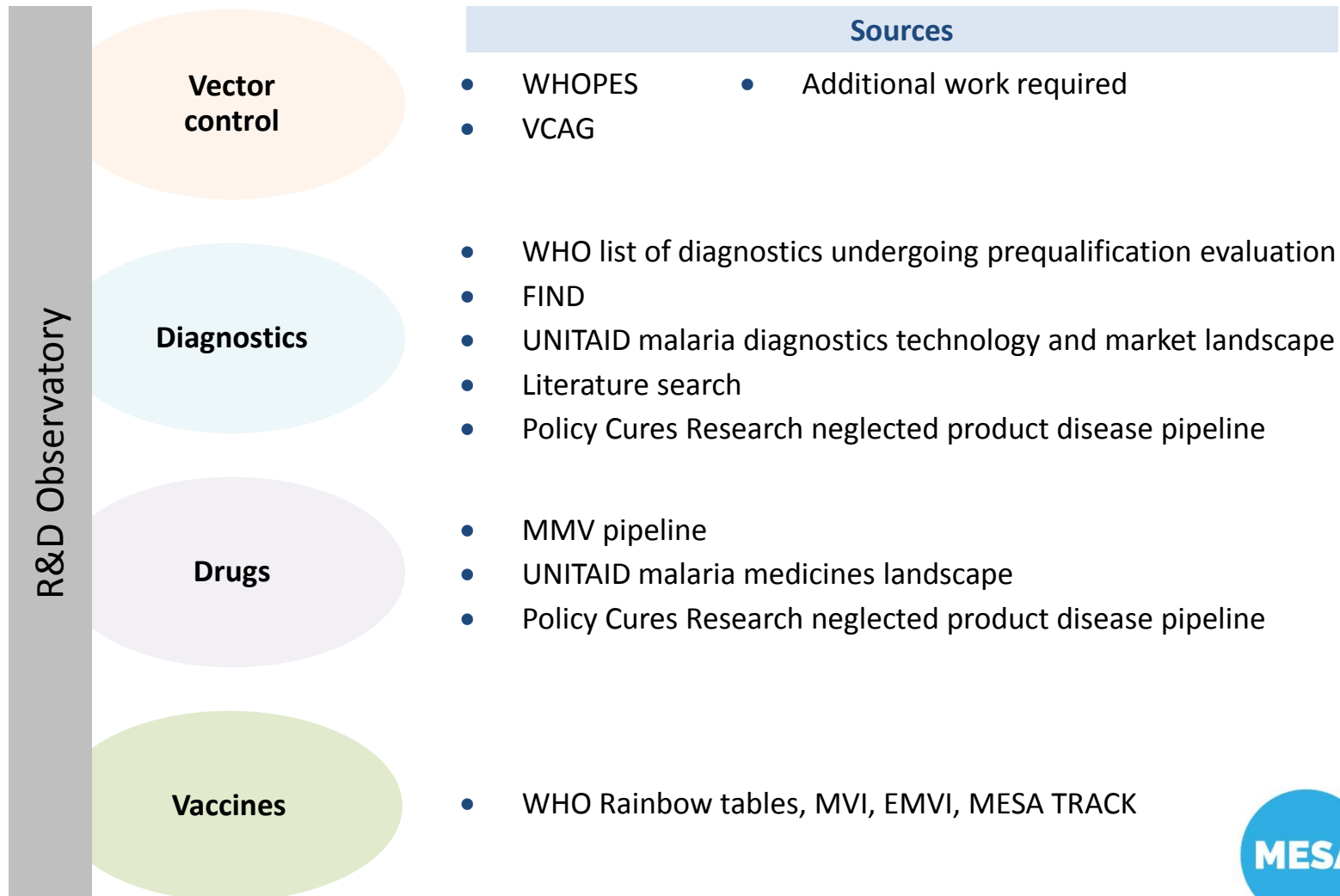
CHALLENGES

- Optimizing and managing adaptations to tools and strategies
- Regions with high transmission intensity
- Residual transmission and accelerating elimination
- Achieving universal access (including the “5th child”)
- Addressing *P. vivax* and non-falciparum species
- Achieving, documenting and maintaining elimination

- **Question 2:** In progress – clarify which types of solutions have
 - **Proof of Concept confirmed** (TPP, evidence of public health relevance)
 - **Public Health relevance To Be Determined**
 - **Other** (e.g. public health relevance disproved)
- **Is this a USEFUL REFINEMENT TO THE PIPELINE?**

Development of R&D priorities: PIPELINE

4. Identify the pipeline



Development of R&D priorities: mapping to the pipeline

5. Existing products in the pipeline mapped onto potential product solutions using heat maps

| Phase | Product | New drug classes used in combination therapies for malaria treatment | New drugs for severe malaria | New drugs for <i>P. vivax</i> radical cure | Drugs for <i>P. vivax</i> radical cure and/ or chemoprevention safe in pregnancy, children and G6PD-deficiency | SERCaP | Novel drugs for chemoprevention | Novel drugs for IPTp | Novel drugs for IPTi, SMC | Endectocides in livestock and humans | New drug combinations suitable for use in MDA/MSAT/FSAT | Transmission-blocking drugs in <i>P. falciparum</i> |
|-----------|---|--|------------------------------|--|--|---------------------------|---------------------------------|---------------------------|---------------------------|--------------------------------------|---|---|
| Marketed† | Arterolane + piperazine | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| Marketed† | Artemisinin + naphthoquine | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| III | Tafenoquine | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| III | Artemether sub-lingual spray | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| III | Co-trimoxazole | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | In HIV | In HIV | In HIV | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | Artefenomel (OZ439) + ferroquine | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | KAF156 + lumefantrine | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | KAF156 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | Cipargamin (KAE609) | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | DSM265 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | Fosmidomycin + piperazine | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | Methylene blue + artesunate/amodiaquine | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | SAR97276 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | Artemisone | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | AQ-13 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | Sevuparin (DF02) | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | MMV048 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| II | Ivermectin | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible |
| I | P218 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| I | SJ733 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Target indication | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| I | ACT451840 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| I | CDRI 97/78 | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |
| I | N-tert butyl isoquine | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible | Not indicated or possible |

Target indication | Possible but not target indication or too early to define | Not indicated or possible



MALARIA ERADICATION SCIENTIFIC ALLIANCE

NB: Heat maps for each product class will require verification by experts

R&D Objectives

6. Based on existing pipeline, potential product solutions classified as to the R&D objective

| Objective | Vector control | Diagnostics | Drugs | Vaccines |
|-------------|---|--|--|--|
| Accelerate | <ul style="list-style-type: none"> Combination LLINs and combination IRS New insecticide classes are urgently needed Novel vector control tools, particularly those targeting outdoor biting or for use in high transmission regions | <ul style="list-style-type: none"> Sensitive and specific diagnostics for <i>P. vivax</i> Affordable, simple and accurate POC tests for G6PD deficiency RDTs that detect and differentiate all <i>Plasmodium</i> species Multiplexed POC tests of acute febrile illness Stable, valid, specific and sensitive RDTs that do not depend on <i>Pfhrp2/3</i> Highly sensitive POC diagnostics for identifying low-density, sub-clinical infection Non-invasive diagnostic tests POC diagnostics to identify drug-resistant parasites POC/health system falsified drug screening | <ul style="list-style-type: none"> New drug classes used in combination therapies for malaria treatment New drugs for severe malaria New drugs for <i>P. vivax</i> radical cure SERCaP Novel drugs for chemoprevention Novel drugs for IPTp Novel drugs IPTi/ SMC Transmission-blocking drugs Endectocides in livestock and humans New drug combinations suitable for use in MDA, etc. | <ul style="list-style-type: none"> Preventive vaccines for <i>P. falciparum</i> Preventive vaccines for placental malaria Transmission-blocking vaccines for <i>P. falciparum</i> |
| Innovate | <ul style="list-style-type: none"> Additional novel vector control tools, particularly those targeting outdoor biting or for use in high transmission regions Gene drive methodologies | <ul style="list-style-type: none"> Diagnostics to identify hypnozoites Affordable, simple and accurate POC tests for pregnancy High-throughput mosquito assays (age, parasites, resistance, host preference) Infectivity/gametocyte POC diagnostics (research only) | <ul style="list-style-type: none"> Drugs for <i>P. vivax</i> radical cure/ chemoprevention that are safe in pregnancy, children and G6PD-deficiency | <ul style="list-style-type: none"> <i>P. vivax</i> targeted preventive and transmission-blocking vaccines New targets for <i>P. falciparum</i> Novel enhanced adjuvants |
| Investigate | <ul style="list-style-type: none"> <i>Wolbachia</i> applications in <i>Anopheles spp.</i> | <ul style="list-style-type: none"> Ultra-low cost lab-on-a-chip technology | <ul style="list-style-type: none"> Alternative drug delivery systems | <ul style="list-style-type: none"> Monoclonal antibodies |

NB: WORK ONGOING – WILL REQUIRE VALIDATION THROUGH CONSULTATION
NOTE: AT THIS TIME THESE ARE JUST “products”, neglects combos, strategies

Question 3: Are more specific or broader recommendations most useful?

Vector control

- A more proactive approach to identifying, assessing and recommending novel vector control methods is needed

Diagnostics

- Evaluation procedures for non blood-based diagnostics are required
- Standardization of procedures to evaluate molecular methods and their use cases are needed

Drugs

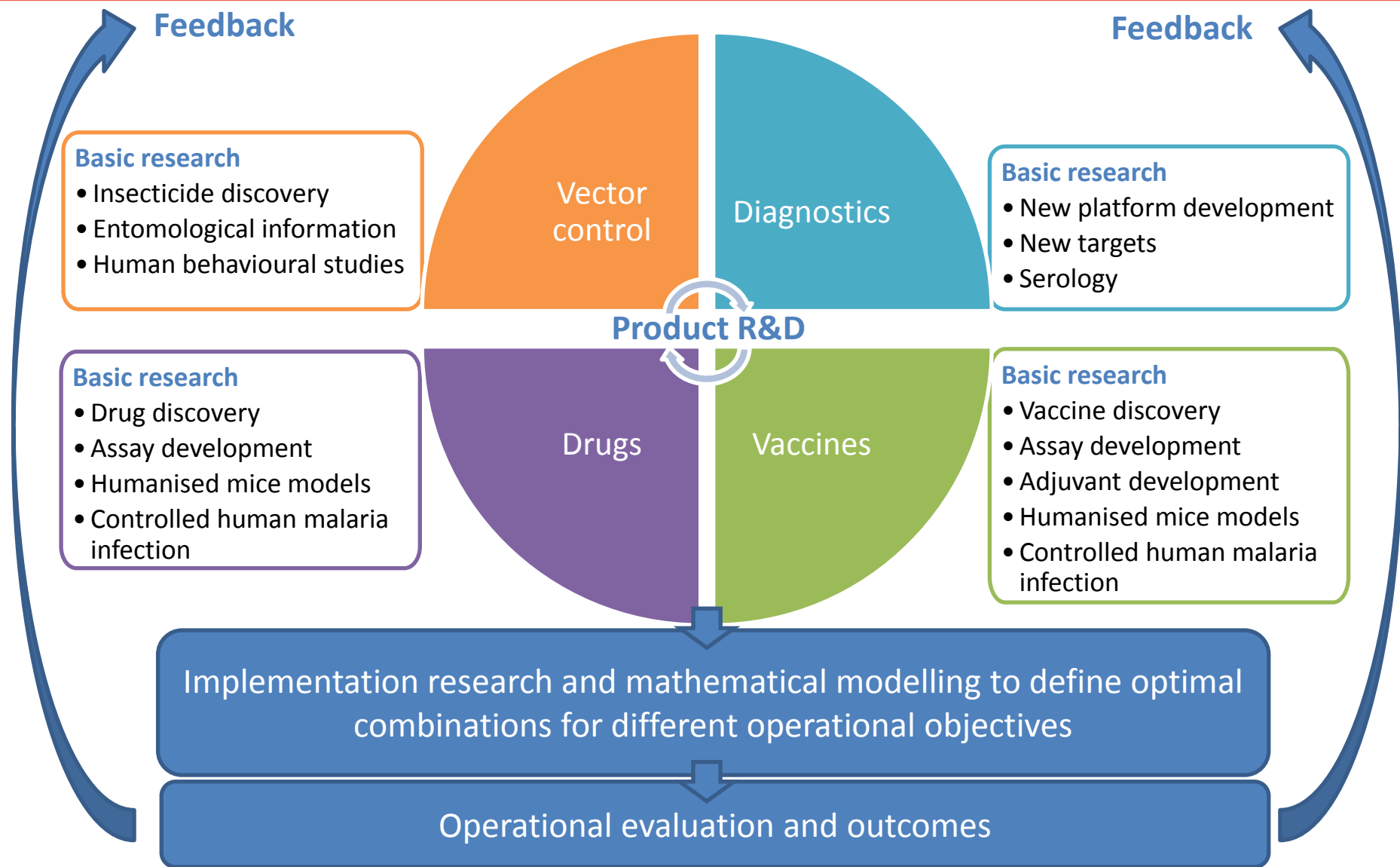
- Opportunities for streamlining assessment and regulatory procedures need to be examined

Vaccines

- RTS,S development needs to be examined and opportunities for the streamlining of assessment and regulatory procedures identified and implemented
- CROSS-CUTTING ISSUES: prioritization and funding for phase 3 trials; regulatory pathway, clinical trial synergies and platforms



General positioning of product R&D in overall R&D requirements



INCLUSIVITY: Basic and Implementation Science

- The developing document already includes sections on scientific feasibility, as well as technical, regulatory and funding issues for each product class

- **Question 4: WE PROPOSE TO INCLUDE IN THE BREADTH OF RESEARCH NEEDS some critical elements of BASIC RESEARCH and IMPLEMENTATION SCIENCE. Feedback?**

Basic science rigorously reviewed in MALERA Refresh.

- Would a more general approach looking at enabling technologies be appropriate?

Implementation science, including operational research and health systems, reviewed in MALERA Refresh

- Could be mapped out to Challenges
- Mindful of potential overlap with regulatory and assessment requirements – needs to be managed?

Development of R&D priorities: CONSULTATION

MalERA consultation process, including engagement of panels

MESA consultation process, including engagement of panels

GMP review

MPAC review – REQUEST that a minimum of 3 reviewers be identified

Web-based consultation

Expert Committee review

Question 5: Are these plans for consultation adequate?

SUMMARY OF QUESTIONS

- **Question 1: Do the challenges and problems identify the top issues that could drive the research agenda?**
 - **Note that basic and implementation science have not yet been mapped**
- **Question 2: We propose to indicate which products have proven public health utility, and those products for which public health utility requires 'POC'**
- **Question 3: Are more specific or general recommendations most useful?**
- **Question 4: We propose to include in the breadth of research needs some critical elements of basic research and implementation science. Feedback?**
- **Question 5: Are the plans for consultation adequate?**

What's coming next?

Products in phase III or large-scale field trials – WORK IN PROGRESS

| Challenge | Vector control | Diagnostics | Drugs | Vaccines |
|---|---|--|---|---|
| Resistance to existing control and treatment | <ul style="list-style-type: none"> • Interceptor® G2 (LLIN)* • PermaNet 3.0® (LLIN)* • Fludora Fusion® (LLIN)* • Sylando® 240SC (IRS) • Lethal house lures • Spatial repellents • Vector traps | <ul style="list-style-type: none"> • Access Bio Pf RDT • Q-POC™ diagnostic test • Scio falsified drug detection • Q-POC™ drug susceptibility test | <ul style="list-style-type: none"> • Arterolane + piperaquin† • Co-trimoxazole (in HIV) | <ul style="list-style-type: none"> • RTS,S and RTS,S fractional dose |
| Regions with high transmission intensity | <ul style="list-style-type: none"> • Lethal house lures • Spatial repellents • Vector traps | | | <ul style="list-style-type: none"> • RTS,S and RTS,S fractional dose |
| Residual transmission and accelerating elimination | <ul style="list-style-type: none"> • Lethal house lures • Spatial repellents • Vector traps | <ul style="list-style-type: none"> • Alere™ Malaria Ag P.f • Access Bio Pf RDT • Q-POC™ diagnostic test | | |
| Accessing hard to reach populations | <ul style="list-style-type: none"> • Lethal house lures • Spatial repellents • Vector traps | <ul style="list-style-type: none"> • Urine Malaria Test™ Pf • Urine Malaria Test™ Pf/Pv | | |
| Addressing <i>P. vivax</i> / <i>P. ovale</i> and other non-falciparum species | <ul style="list-style-type: none"> • Lethal house lures • Spatial repellents • Vector traps | <ul style="list-style-type: none"> • Urine Malaria Test™ Pf/Pv • Q-POC™ diagnostic test • Rapid Assessment of Malaria (RAM) • Magneto-optical Device (MOD) • (PATH G6PD Initiative) POC • (PATH G6PD Initiative) RDT | | |
| Defining and maintaining elimination | <ul style="list-style-type: none"> • Interceptor® G2 (LLIN)* • PermaNet 3.0® (LLIN)* • Fludora Fusion® (LLIN)* • Sylando® 240SC (IRS) • Lethal house lures • Spatial repellents • Vector traps | <ul style="list-style-type: none"> • Urine Malaria Test™ Pf • Urine Malaria Test™ Pf/Pv • Alere™ Malaria Ag P.f • Access Bio Pf RDT • Q-POC™ diagnostic test | <ul style="list-style-type: none"> • Arterolane + piperaquin† | <ul style="list-style-type: none"> • RTS,S and RTS,S fractional dose |

*None of these are a combination of two novel insecticides, so do not strictly meet the requirements for LLINs and IRS using combinations of two new drug classes, so should be regarded as an interim measure. LLINs and IRS that do not include combinations should not be prioritized.

†This is not a combination of two novel drug classes, and will only be of use where piperaquine resistance is absent as an interim measure.

‡ Preventive efficacy of RTS,S and RTS,S fractional dose is insufficient to allow scale back of other malaria control and prevention activities and will not influence transmission. The dosing schedule is not suitable for use in hard to access populations.



Background: Contents list for full report (DRAFT)

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