

MALARIA VACCINE PILOTS

BOARD MEETING
Judith Kallenberg
22-23 June 2016, Geneva

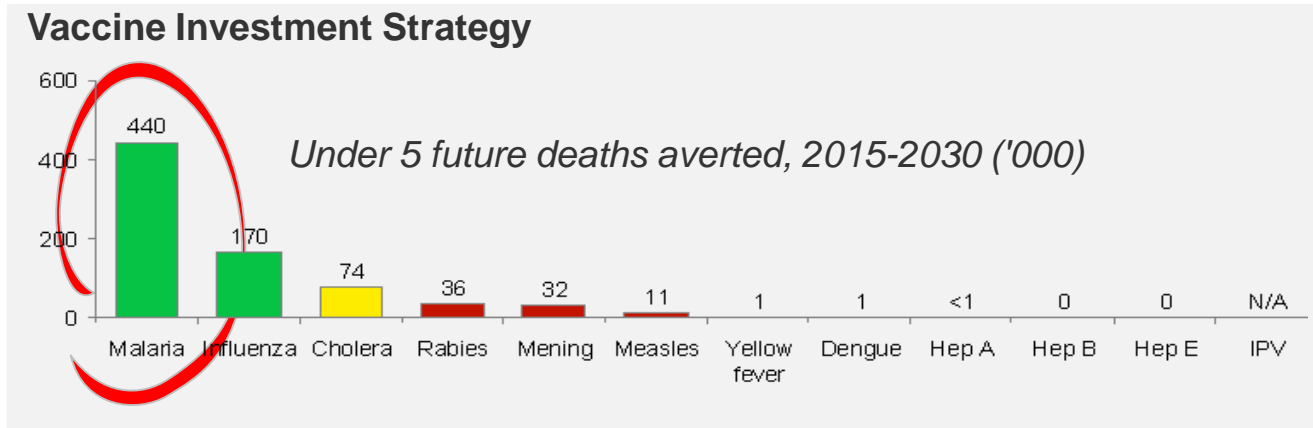


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Developments since 2013 (1/5)

2013

- Malaria vaccine 'shortlisted' in Vaccine Investment Strategy
- Board decision deferred until after trials are complete



Developments since 2013 (2/5)

2015

- Publication of trial results
 - 39% efficacy after 4 doses (with high bednet coverage)
 - Unable to measure mortality impact
 - No serious adverse events
 - Questions on meningitis and cerebral malaria
- European Medicines Agency issued 'positive scientific opinion'

THE LANCET

Efficacy and safety of RTS,S/AS01 malaria vaccine with or without a booster dose in infants and children in Africa: final results of a phase 3, individually randomised, controlled trial



*RTS,S Clinical Trials Partnership**

Developments since 2013 (3/5)

2015

- WHO recommendation for large scale pilot
- Gavi Board advises to engage in WHO-led process to prepare for the pilots, together with other potential funders



Developments since 2013 (4/5)

2016

- Gavi, UNITAID, Global Fund joint engagement with WHO



WHO Malaria Vaccine Pilot proposal

Initial implementation of a newly licensed vaccine

Purpose

- Demonstrate operational feasibility of 4 dose-schedule
- Assess impact on mortality in real-life settings
- Additional data on potential adverse events

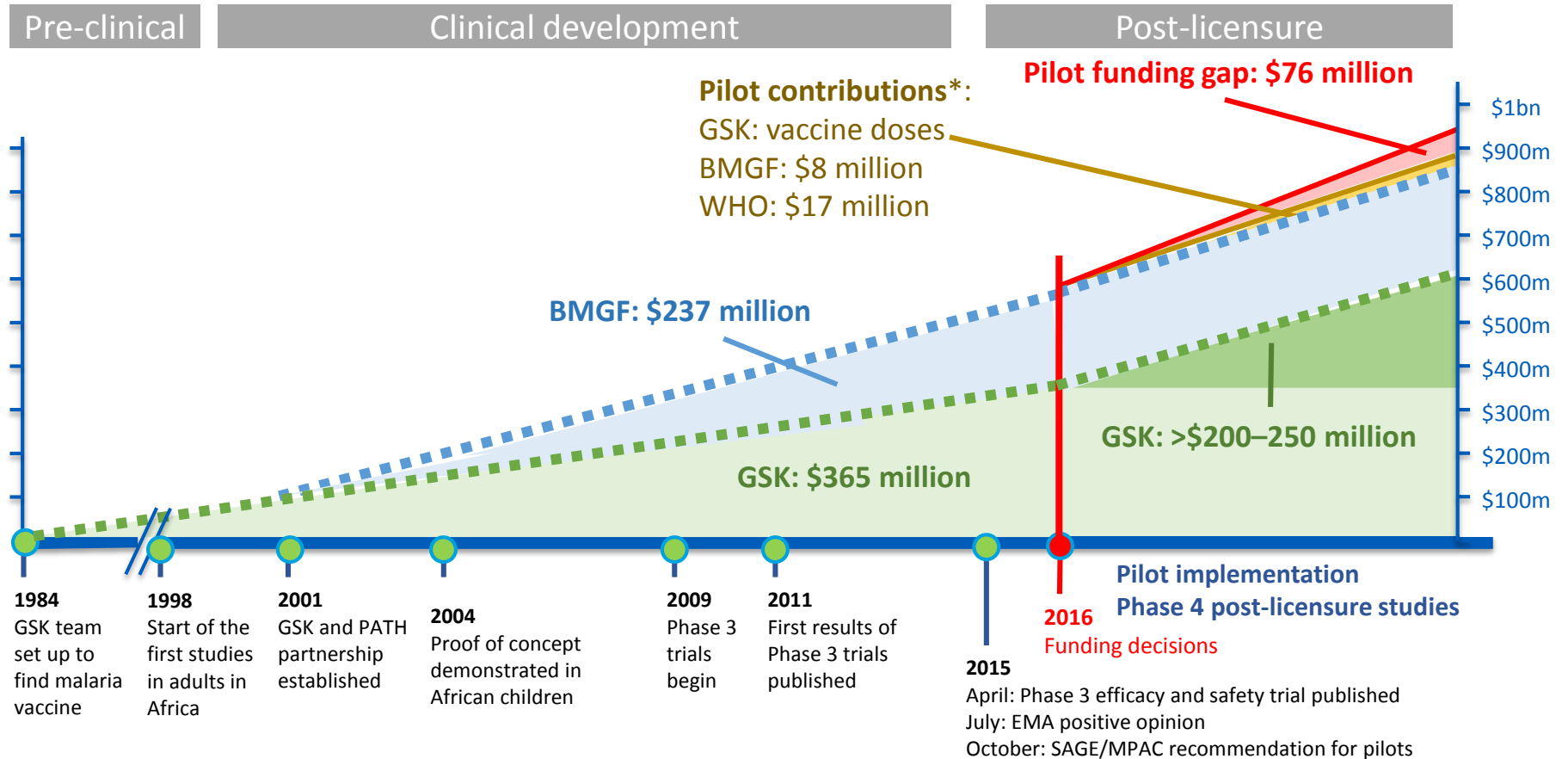
Led by WHO with support from PATH

- Programme Advisory Committee with SAGE and MPAC members
- Programme Safety Committee
- Funders Forum

Funding gap

Phase 1	Phase 2	Total
US\$ 55 m	US\$ 21 m	US\$ 76 m

Malaria vaccine investments to date



Cumulative investments are illustrative and may not reflect precise cash flows

**Some co-funding contributions are not reflected in the graph, such as in-kind contributions by pilot countries (e.g. frontline health workers, supply chains, supervision and information systems)*

Developments since 2013 (5/5)

2016

- PPC: recommendation to co-fund the pilots
- AFC: funding in accordance with Programme Funding Policy
- External Review Committee: budget is reasonable value for money, cost reductions of at least 10% possible

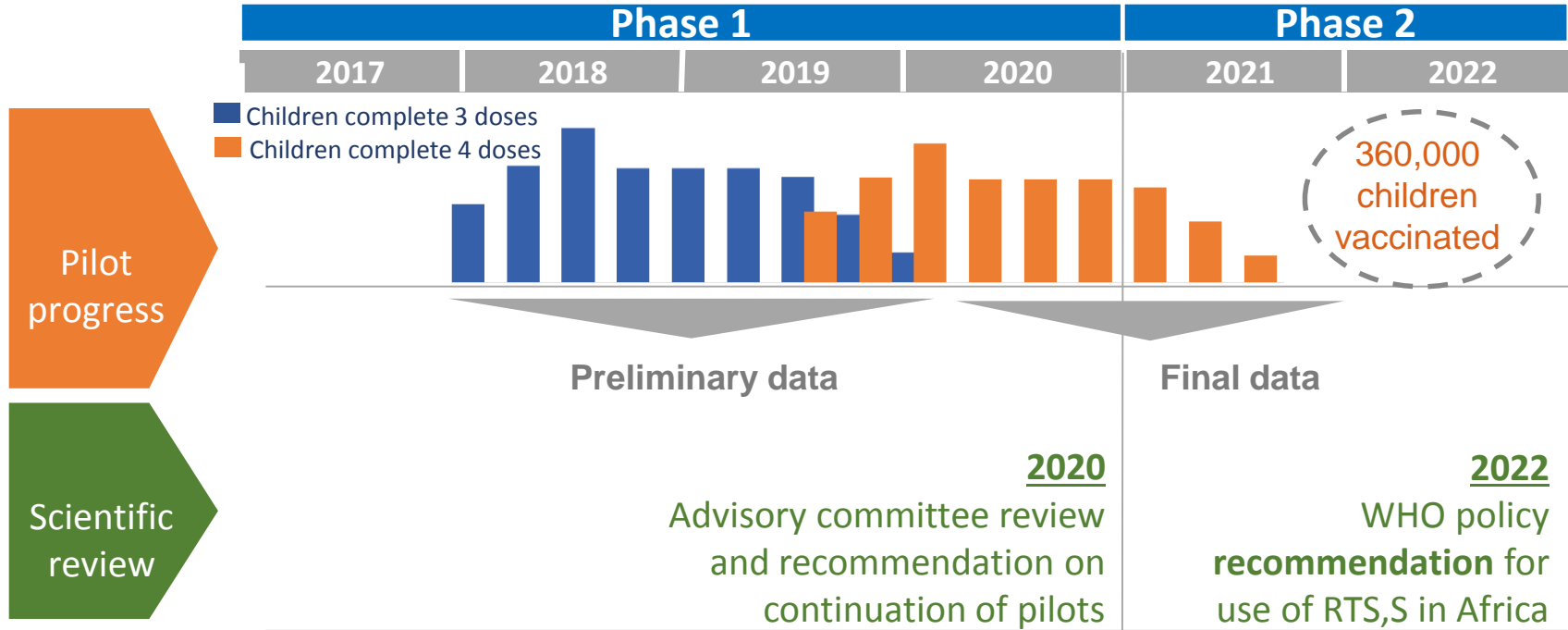
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**Terms of Reference (ToR) for Review Committee
Review of the WHO RTS,S/AS01 Malaria Vaccine Pilot Implementation Proposal**

1. Background

The Gavi Secretariat seeks to undertake a review to obtain external advice on the financial details of a WHO proposal for the implementation of the “RTS,S/AS01” Malaria Vaccine Pilot, as per the WHO recommendation published in January 2016¹. The proposal has been

Pilot milestones



Pilot progress

Scientific review

Risks

Raising expectations

- pilot support perceived as guarantee for future Gavi funding window

Setting a precedent

- pilot support for other vaccines

Opportunity cost

- not included in Investment Opportunity

Considerations for a funding commitment

Relevant past experience

- ADIPs, HPV demonstration, rabies and cholera vaccine studies

Considerations

- collective cost-sharing for LIC vaccine development
- advance the science on a potential malaria vaccine

Recommendations (1/2)

The Gavi Programme and Policy Committee recommended to the Gavi Board that, using available resources from the current strategic period, and contingent upon WHO securing funding from other sources to fully finance the Malaria Vaccine Pilots, it:

- (a) **Approve** in principle an amount of up to US\$ 27.5 million (equivalent to half of the funding request) for Phase 1 of the WHO-led Malaria Vaccine pilots to be implemented during 2017-2020; and

Recommendations (2/2)

(b) **Note** that this investment is contingent upon:

- i. Other funders contributing an equivalent amount to cover the pilot costs
- ii. Independent review of the proposed budget amount ensuring that this is being done as cost effectively as possible
- iii. Further assessment of the selection of pilot settings
- iv. Close engagement with the Global Fund and UNITAID including through the proposed Funders Forum
- v. WHO seeking input from Alliance partners in the planning and implementation of the pilots
- vi. Communication that this investment is for implementation evaluation of a newly licensed vaccine as distinct from R&D
- vii. Clear communication that this recommendation does not constitute a precedent for future funding related to the implementation of the malaria vaccine regardless of the outcome of the pilots, nor for future funding of similar pilots for other vaccines
- viii. Regular reports to the PPC, and a detailed report to the PPC and Board on progress no later than 2019

THANK YOU



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