MalVax Alliance

1 July 2026

Annex C: Technical Scope for Modelling Working Group

Version	3.0 — Final
Date	1 July 2026
Status	Provisional — Establishment Year
Relates to	MalVax Alliance Working Group Terms of Reference (Umbrella TOR)

1. Summary Goal

The MalVax Alliance brings together the malaria vaccine R&D community to efficiently and effectively accelerate progress on urgently needed next generation vaccines. The MalVax Modelling Working Group ("Modelling WG") will establish a **collaborative modelling forum** that connects modelling groups and the broader malaria vaccine R&D community. The WG will synthesise the current state of modelling, identify priority questions with partners, and support the modelling community to collaborate with leading vaccine candidates in Phase 2 and 3 development. Through an open, community-oriented forum, the WG will help translate modelling insights into practical guidance that serves developers, trialists, regulators, and policy-makers at country and international levels.

2. Background and Rationale

More than 150 members of the malaria vaccine research and development community met during side meetings of the 2024 and 2025 ASTMH conferences. The meetings identified that as novel malaria vaccines continue to advance through the development pipeline, that coordinated modelling could support several of the critical challenges identified to accelerate next-gen malaria vaccine development.

Mathematical modelling has played an important role in malaria vaccine research and development, providing critical evidence for the population-level impact of both licensed malaria vaccines, RTS,S/AS01 and R21/Matrix-M, and directly informing policy recommendations and implementation strategies. The consultations identified that modelling can be a key partner in supporting vaccine development decisions from early candidate prioritisation through to regulatory review and post-licensure deployment. And that modelling could further support our understanding of which vaccine characteristics matter most across diverse transmission settings, how trial endpoints, timing and design, might be optimised to support translation and impact estimates, and how efficacy findings translate into real-world public health benefit.

As novel malaria vaccines continue to advance through the development pipeline, the need for coordinated, high-quality modelling has never been greater. Yet despite significant modelling capacity within the malaria R&D community, this work remains siloed and possibly uncoordinated across clinical and modelling groups: outputs are not standardised, linkage to trial design and regulatory pathways is often ad hoc, modelling often comes late in clinical trials, and integration with early clinical and immunological data is insufficient. Modelling has been underutilised precisely at the stages where it could add the most value.

The Modelling WG will address this directly by connecting modelling groups with vaccine developers through a structured forum and engaging them far earlier in the clinical development process than has previously been the norm. By aligning on priority questions and standardised outputs, and

ensuring that modelling evidence is accessible and actionable for developers, trialists, regulators, policymakers, and implementers alike, the Working Group will ensure that the field's proven modelling capabilities are fully mobilised in support of the next generation of malaria vaccines.

3. Scope and Priority Deliverables (June 2027)

By June 2027, the Modelling WG will have **established a functioning modelling forum**, produced a clear map of the current landscape through a scoping survey, and delivered consensus on priority questions and standardised outputs to support and accelerate the next-generation malaria vaccine field. The WG will have supported at least two modelling groups to support at least two leading vaccine candidates in Phase 2 or to prepare for multiple modelling groups to support needed analysis for Phase 3 clinical development and policy needs. In addition, the WG will have produced or substantially advanced a state of the field paper for peer review. Progress and key outputs will be **presented for community feedback at the inaugural MalVax Scientific Conference (February 2027)**. Scope and deliverables anticipated to inform the February Conference are indicated below (Section 4).

3.1. Forum establishment and community engagement

- **Modelling forum launched,** with an initial membership drawn from across modelling groups and the broader R&D community.
- **Scoping survey completed,** mapping existing modelling capacity, approaches (vaccines and monoclonals), and community priorities.
- **Forum resources developed,** including short list of background reading and guidance for new participants (will link to state of the field paper, 3.2).

3.2. State of the field informed by modelling forum

- **Draft state of the field paper** describing how modelling has been utilised for malaria vaccine clinical trial analysis and used to support evidence on the potential impact and cost-effectiveness of malaria vaccines for policy recommendations, funding, and other malaria strategy decisions. It will include commentary on, lessons learnt from past modelling and how modelling can support new candidates in development and clinical trials, clinical trial design and endpoints, and a forward-looking perspective on priorities: How we can accelerate modelling evidence for next-gen vaccines given lessons learnt and identified gaps integrating modelling with data and partners across the broad range of decisions on new vaccines. The paper will build upon previous literature including, Galactionova *et al.* (2021) and Birkett *et al.* (2025)[1][2], and is intended for submission to a peer-reviewed journal.
- **Draft mapping of prioritised research questions and roadmap:** collate and map important modelling questions in consultation with the modelling forum for next-generation malaria vaccine development, and produce a prioritisation and roadmap those the WG with MalVax community can address, with indicative timelines and dependencies.

3.3. Vaccine candidates support

- **Modelling support initiated for at least two leading candidates**, building on emerging efficacy and other clinical data.

[1] Galactionova, Katya, Thomas A. Smith, and Melissa A. Penny. "Insights from modelling malaria vaccines for policy decisions: the focus on RTS, S." *Malaria journal* 20.1 (2021): 439.
[2] Birkett, Ashley J., et al. "Value profile for Malaria vaccines and monoclonal antibodies." *Vaccine* (2025): 127971.

- **Pathway developed for multi-group collaboration** on Phase 3 support (including Clinical Endpoints support) and for impact and economic assessments for next-gen malaria vaccine candidates.

4. MalVax Scientific Conference, February 2027

The following outputs from the Modelling WG will contribute to the inaugural MalVax Scientific Conference anticipated in the first week of February 2027:

- **Presentation and community discussion of the draft state of the field paper and mapping (3.2)** — seeking input on priorities and questions informing the forward-looking research agenda.
- **Update on the modelling forum** — membership, resources, and early learnings from the scoping survey.

The WG Co-Chairs will engage with the MalVax Scientific Conference Planning Committee to ensure modelling topics are well represented in the programme and that the forum concept is introduced to the broader community at the conference.

5. Beyond June 2027

Following the establishment period, the Modelling WG will build on its early work to:

- **Systematically share modelling learnings** that support clinical trial thinking and design across the community.
- **Use modelling to provide ongoing support** to clinical trial endpoints within other Working Groups.
- **Develop prioritised research questions and roadmaps** for the next phase of the MalVax Alliance's work, e.g. if modelling would inform implications of evolving regulatory guidance for trial designs, ways to systematize data sharing across the community, informing multi-component vaccine candidates with different composition for different transmission settings and age/population groups, and/or co-authoring publications with other WGs such as on trial endpoints.
- **Expand the forum progressively** with sub-groups and deeper inclusion of non-modellers and implementation-focused stakeholders.

6. Collaboration

6.1. Other MalVax Working Groups

The Modelling WG has a cross-cutting role within the MalVax Alliance. It will work closely with:

- **Endpoints WG:** providing modelling input to trial design and endpoint prioritisation, and co-authoring outputs.
- **Assays WG:** linking immunological readouts to model parameters and population-level outcomes.

A named Modelling WG liaison identified by the Co-Chairs will participate in cross-WG coordination meetings, and the WG will share draft outputs with other WGs for comment before finalisation.

6.2. Existing WHO Guidance

The Modelling WG will take stock of and build on existing WHO guidance, including:

- *Malaria Vaccines: Preferred Product Characteristics and Clinical Development Considerations* (WHO, 2022)
- *Guidelines on the Quality, Safety and Efficacy of Recombinant Malaria Vaccines Targeting the Pre-Erythrocytic and Blood Stages of Plasmodium falciparum* (WHO, 2020)

WG outputs will be designed to complement, not duplicate these documents, with a focus on practical, community-facing guidance that goes further into implementation and methodology.