Vector Control Advisory Group

Vector Control Advisory Group (VCAG) Standard Operating Procedures

1. Background

Independent evaluation of the public health value of new tools, technologies and approaches (collectively referred to as "interventions") for vector control provides the foundation for the development of recommendations by the World Health Organization (WHO) as communicated via guidelines. Such guidance aims to support the optimal use of the scarce resources for vector-borne disease control by WHO Member States. To assist WHO in the independent evaluation, the Vector Control Advisory Group (VCAG) provides guidance to applicants on developing the evidence base required to assess the public health value of new interventions, and conducts the assessment of data once available.

Entities seeking a WHO assessment of the public health value of a new intervention are invited to submit a Request for Determination of Pathway form to pqvectorcontrol@who.int.[1] The submission will be reviewed by the WHO Pre-submission Coordination Committee (PCC) to determine the applicable WHO evaluation pathway. Interventions that do not fall under an intervention class covered by a WHO recommendation will be subject to evaluation through the new intervention pathway. In this pathway, evidence of public health value must be established before WHO will develop a recommendation for such an intervention class. In entering the new intervention pathway, applicants will be supported through the assessment of public health value, as outlined in this document, with the support of the WHO VCAG Secretariat. The assessment of quality, safety and entomological efficacy is supported via the prequalification pathway, for which information on processes is provided elsewhere.[2]

1 Determination of pathway. In: WHO – Prequalification of Medical Products [website]. Geneva: World Health Organization (https://extranet.who.int/pqweb/vector-control-products/determination-pathway, accessed 4 July 2022).

2 Vector control products. In: WHO – Prequalification of Medical Products [website]. Geneva: World Health Organization (https://extranet.who.int/pqweb/vector-control-products, accessed 4 July 2022).

World Health Organization

1.1. Functions of VCAG

VCAG has the following specific functions:

(a) To support WHO in guiding applicants, via the WHO VCAG Secretariat, on study designs for the generation of epidemiological data intended to enable assessment of the public health value of new vector control interventions;

(b) To support WHO in evaluating the public health value of new vector control intervention classes, based on epidemiological studies submitted to WHO;

(c) To advise WHO (i.e. the relevant technical departments) on whether public health value has been demonstrated for a new vector control intervention.

For more information on the role of VCAG, see the full Terms of Reference.[3]

1.2. New intervention pathway

Once it has been determined that an intervention falls into an intervention class not covered by a WHO recommendation (and is therefore assigned to follow the new intervention pathway), applicants are invited to initiate contact with the VCAG Secretariat, via the vcag@who.int address, should they wish to proceed with the evaluation process. The WHO VCAG Secretariat will then organize an initial meeting to hear more about the intervention and the status of evidence generation, and to discuss what is to be expected during the first and subsequent interactions with VCAG. A general overview will be provided regarding meeting procedures, typical submission requirements, and relevant timelines for the meeting (see Annex 1), as well as the overall evaluation process. It is common for applicants to make successive submissions, updating VCAG on their progress and challenges over time, as the evidence base for assessing the intervention's public health value is being generated.

The review of the submission package takes place in advance of the VCAG meeting. The submitted material is reviewed in detail by a working group comprising a subset of VCAG members. This working group is responsible for leading the review; other members are welcome to provide additional input and feedback during the meeting. At the meeting, applicants make a presentation to VCAG, summarizing the intervention, target disease(s) and status of the trial(s), with appropriate supporting materials. A question and answer (Q&A) session provides applicants with an opportunity to ask for advice, and for VCAG to seek clarification on particular aspects of the work, as needed. Following this interactive session, the working group leads a closed discussion with the rest of the VCAG members and any invited ad hoc expert advisors. Preliminary feedback is consolidated and shared with applicants before the end of the meeting; however, the formal evaluation and advice are provided to the applicants only in the form of the official meeting report, published two to three months after the VCAG meeting.

It should be noted that, at all times, communication between applicants and VCAG members relating to VCAG activities is to take place via the WHO VCAG Secretariat. Applicants are not permitted to contact any member of the advisory group (in relation to VCAG activities) without the approval of the Secretariat. Any approved communication that does take place must include the Secretariat in copy. While

3 VCAG Terms of Reference (https://www.who.int/groups/vector-control-advisory-group/about)

applicants will inevitably communicate with VCAG members during meetings, and in some cases between meetings (i.e. as part of off-cycle reviews), official communication relating to the assessment of any intervention is provided only through the WHO VCAG meeting report. To this effect, communication relating to off-cycle reviews will be incorporated into the report of the meeting following the interaction.

2. Evaluation of public health value of an intervention

The criteria by which WHO evaluates an intervention within the vector control evaluation process are described in WHO's *Norms, standards and processes underpinning the development of WHO recommendations on vector control*.[4] By contrast, the current document details the steps, processes, submission documents and administrative requirements needed as part of that evaluation process.

Evidence generated to demonstrate public health value is reviewed by VCAG members either during the biannual meetings or, exceptionally, in off-cycle reviews.

2.1. VCAG meetings

2.1.1. Planning and timeline

WHO will generally convene two VCAG meetings annually (either in-person or virtually); this frequency may be adjusted as necessary. The standard timeline for the meeting preparations and development of the meeting report is outlined in Annex 1.

Three months before a VCAG meeting, the WHO VCAG Secretariat will reach out to applicants to find out whether they are interested in participating in the upcoming meeting. The call will be made to applicants who have previously participated in a VCAG meeting (except for those who have formally withdrawn) or who reached out to VCAG following assignment to the new intervention pathway by the PCC. Applicants will need to confirm their interest in participating 10 weeks in advance of the meeting to vcag@who.int.

Responses to the call should briefly describe the progress made by the applicant group and what they plan to present at the meeting. A template for responses is provided for the applicants. The WHO VCAG Secretariat will then determine whether the applicants' participation in the upcoming meeting is warranted and feasible (based on agenda capacity), and formally request submissions from those who can be accommodated on the agenda.

The invitation to participate and make a submission will include the application form for that meeting and related instructions for the actual submission. Submissions must be received in full by the Secretariat six weeks in advance of the scheduled start of the meeting.

Efforts will be made to accommodate all applicants on the agenda should the proposed submission be suitable for VCAG's review. However, if some prioritization

4 Norms, standards and processes underpinning the development of WHO recommendations on vector control. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/338030, accessed 4 July 2022).

of submissions is necessary, the Secretariat will inform any applicants who cannot be accommodated and provide information about the next opportunity to make a submission. No applicant should make a submission without an explicit invitation from the Secretariat.

2.1.2. Documentation for VCAG review

A VCAG submission will always include a completed VCAG Evaluation and Tracking Form, a slide deck for the presentation, and supporting documents and information as necessary (which may consist of draft/final epidemiological trial protocols, statistical analysis plans, standard operating procedures, preliminary or final trial results, and potentially any peer-reviewed publications stemming from the work). Together, these documents form the basis for the VCAG review.

The WHO VCAG Secretariat will provide applicants with the necessary, latest versions of all forms and templates before each meeting. Applicants are to use only the versions provided to them in the formal invitation for that meeting; previous versions of the application form will not be accepted. The documents that applicants need to submit in advance of the meeting will depend on the status of the intervention in the evaluation process, as outlined below.

a) New applicants should submit:

- completed VCAG Evaluation and Tracking Form;
- presentation for VCAG, based on the PowerPoint template;
- supporting documents (such as those indicated above, as appropriate for the stage of evidence generation for the intervention).

b) Returning applicants (those who have participated in at least one meeting already) should submit:

- completed VCAG Evaluation and Tracking Form outlining any activities conducted and outcomes achieved since the previous submission;
- presentation for VCAG, based on the PowerPoint template;
- supporting documents (such as those indicated above, as appropriate);
- a summary of the extent to which any VCAG recommendations made in the previous meeting report have been addressed;
- full version details for any previously submitted documents, with a summary of changes made to relevant documents, and the documents themselves with tracked changes (to expedite VCAG's identification of relevant changes).

All applicants are requested to use the VCAG PowerPoint template to present their work at the meeting. The template provides an outline of useful information for applicants to share with VCAG during their interactions; however, it can and is encouraged to be adapted to meet applicants' needs and the appropriate stage of

evidence generation. In the presentation to VCAG, it is unnecessary to include detailed information about how the intervention works, as this information will have already been provided as part of the VCAG Evaluation and Tracking Form and supporting information, or in previous meetings. The presentation is an opportunity for applicants to provide a comprehensive overview of their work (including updates as necessary), address key points, such as how they have responded to VCAG recommendations, and raise any specific questions or topics on which they are seeking VCAG advice.

Applicants must submit their completed VCAG Evaluation and Tracking Form, supporting documentation and PowerPoint template six weeks before the meeting. Usually this is done via an online platform (such as OneDrive) that restricts access to specified persons only (as delegated by the lead applicant[s] of a group). Following submission, the WHO VCAG Secretariat will confirm receipt of the application form and the list of supporting documents received by email within 48 hours.

It is the applicants' responsibility to submit high-quality, complete documentation. If applicants submit documentation that is incomplete or of poor quality, the WHO VCAG Secretariat will request that applicants revise the documentation and resubmit without delay in order to maintain the established timeline leading up to the meeting. Following an internal review of the documentation and confirmation that the submission is complete and of high quality, the documentation will be shared with the working group and co-chairs (except when there are established conflicts of interest) four weeks in advance of the meeting.

2.1.3. VCAG convenings

VCAG meetings may consist of closed and open sessions. General information stakeholder sessions may also be held alongside these.

Closed sessions: Closed sessions in VCAG convenings may be attended by VCAG members and essential WHO VCAG Secretariat only. All VCAG members must have completed a series of documents (as listed in section 4, Administrative requirements) in order to participate. Closed sessions at VCAG meetings are held to discuss and decide on the advice that VCAG offers to the applicants. Dedicated closed sessions may also be held to discuss specific topics that are relevant only to VCAG members, or on which WHO has requested VCAG advice.

Open sessions: In the context of VCAG, open sessions are intended for applicants to present planned, ongoing or completed trials and seek advice in a confidential setting. Attendance at VCAG open sessions is for applicants, their named collaborators, VCAG members, observers, the WHO VCAG Secretariat and affiliated staff, if necessary. Declarations of Interest (DoI) and Confidentiality Undertaking (CoU) forms will be required from all observers attending open sessions.

For these applicant interactions, the duration of each session will be determined based on the status of the applicants' trial and the complexity of their submission, at the discretion of the WHO VCAG Secretariat and in consultation with the co-chairs. For example, applicants providing an interim update on an ongoing trial may be allocated less time than applicants presenting and seeking advice on a new study protocol, or those presenting final trial results.

Occasionally, more general presentations or discussions may also be held in open sessions, enabling wider participation. Attendance at each open session of the meeting is by invitation only and at the discretion of the Secretariat; invitation to one open session does not imply that attendance is allowed at all open sessions.

Stakeholder information sessions: Although not formally part of the advisory group proceedings (as it is outside of the group's functions), VCAG meetings bring together numerous experts, manufacturers, innovators and researchers in the field, thus offering an opportunity to provide a general information session to interested stakeholders. These sessions may involve presentations or updates on WHO recommendations or guidelines in the field of vector control, or other relevant topics. They also enable VCAG to interact with applicants and other interested stakeholders. There are no requirements for any participants to complete any administrative documents to attend these sessions.

2.1.4. Meeting report

After each VCAG meeting, the working group supporting the assessment of a specific intervention will prepare a summary of the discussions held during the meeting, including VCAG's guidance to applicants, and any recommendation to WHO on the public health value of the intervention evaluated (when and where appropriate). For sections not involving applicant submissions and evaluations, the VCAG Secretariat assists with the drafting. The Secretariat reviews each section of the drafted report for consistency and coherence.

Individual sections of the draft report relevant to each submission evaluated are then shared with the applicants for review before publication. This review serves to avoid accidental publication of factual inaccuracies or proprietary information; it is not for applicants to edit or remove specific guidance or advice given by VCAG.

Following applicant review of the respective drafted sections, the report in its entirety will be shared with all VCAG members for review and consensus on the recommendations. Finally, the Secretariat will undertake a final round of review and editing. The report is then finalized and published two to three months after the meeting.

The final meeting report will provide a summary of the intervention reviewed at the meeting and a record of VCAG's advice and guidance to each applicant, as provided during scheduled biannual meetings and off-cycle reviews.

The published meeting report represents the final, official outcomes of the meeting in terms of VCAG's guidance to applicants and its advice to WHO regarding the respective interventions evaluated during that meeting.

2.2. Off-cycle reviews

If applicants have an *urgent* need for VCAG evaluation of study documents, they may submit a request for an off-cycle review. The WHO VCAG Secretariat will consider this request in consultation with the VCAG co-chairs and the working group lead as necessary, with respect to predetermined criteria as listed below. It will be the

final decision of the WHO VCAG Secretariat as to whether the off-cycle review is warranted and can be facilitated.

2.2.1. Justifications for an off-cycle review

The WHO VCAG Secretariat will review the following checklist and the timeline provided in Annex 2 to determine whether the request for an off-cycle review may be accepted. The WHO VCAG Secretariat is not obligated to facilitate any request for an off-cycle review.

1) **Rationale for urgency of the review:** Applicants need to provide adequate justification, explaining the grounds for requesting an urgent review of materials (i.e. why review of the materials cannot wait until the next meeting).

2) **Scope of the review:** The scope of the request must warrant convening the working group off-cycle to review and evaluate the submitted material.

3) **Number of off-cycle reviews per year:** Applicants will be asked to limit the number of requests for off-cycle review to one per calendar year.

4) **Timing:** The submission of documents for an off-cycle review must be received:

    a. more than one month *after* the last meeting (allowing time for the previous meeting report to be developed), and

    b. at least three months *before* the next scheduled meeting (enabling the required preparations for the next meeting, and the forthcoming submissions within the standard review cycle).

    Requests for an off-cycle review must consequently be received in advance of these submission deadlines, in accordance with the timeline in Annex 2.

5) **Previous engagement with VCAG:** Applicants new to VCAG will need to interact with VCAG at one of the scheduled biannual meetings prior to having any documentation reviewed off-cycle.

6) **Respect for VCAG workload:** Individuals within working groups may not be requested to complete more than one off-cycle review within a given inter-meeting period, out of respect for their voluntary contributions of time and expertise to the advisory group.

7) **Quorum of working group:** A minimum of 50% of the previously established working group (from when the applicants last participated in a VCAG meeting) must be available to review the submitted documents.

8) **Multiple requests within an inter-meeting period:** If the Secretariat receives requests for off-cycle review from multiple VCAG applicants in the same period, priority will be given to those applicants who made the request first and to those for whom the minimum quorum of the working group is available (considering point 6 above, as well).

If an off-cycle review is carried out on materials that were previously reviewed by VCAG, applicants should indicate clearly what changes have been made and on which points they seek VCAG's advice.

Results of trials will, in general, not be reviewed off-cycle, as discussions of the results will benefit from direct interaction between applicants and members. Exceptions will be made in cases where this procedure would introduce considerable delays (more than three months) in presenting the findings to a WHO Guideline Development Group to inform the potential formulation of a WHO recommendation.

Applicants should endeavour to keep the WHO VCAG Secretariat informed of upcoming submissions of trial results, so that arrangements to accommodate the submission in an upcoming meeting can be made (thereby avoiding an off-cycle review if possible).

2.2.2. Initiating a request for an off-cycle review

Applicants must submit a written request to the WHO VCAG Secretariat via email (vcag@who.int), outlining the rationale and urgency for an off-cycle review. The request should indicate the last time the applicants participated in a VCAG meeting, provide a summary of status of the trial(s), and indicate the study documents intended for submission and review. As the off-cycle review process moves quickly, applicants should be in a position to confirm that these documents are/will be ready for imminent submission before submitting the formal request.

Where possible, the WHO VCAG Secretariat should be informed (even informally) of the intention to submit an off-cycle review request as soon as the applicants know this might be a possibility. This will assist all parties with the relevant planning, communication and coordination.

2.2.3. Procedures during an off-cycle review

If the request for an off-cycle review is deemed justified and can be facilitated, the VCAG secretariat will provide instructions for the applicants to make their invited submission. No documents should be submitted without prior invitation.

During an off-cycle review, the relevant VCAG working group reviews the VCAG application form and associated materials submitted by the applicants electronically. Under exceptional circumstances, the applicants may be invited to provide a short presentation to VCAG, if it is deemed valuable/necessary by the working group and/or of the WHO VCAG Secretariat.

The working group will review the submitted documents and give *provisional* advice to the applicants, via the WHO VCAG Secretariat, in the form of a draft report of the evaluation. At the next meeting, the lead of the working group will give a short presentation to the rest of VCAG on the off-cycle review and its outcomes.

As only two meeting reports are published annually, the official outcome from the off-cycle review will be incorporated into the subsequent meeting report; there will be no interim publication of the off-cycle review between meetings. Therefore, any draft provided to the applicants following the off-cycle review is provisional and may be subject to final input from VCAG members, before standard review and editorial procedures as part of the meeting report development.

3. Roles, expectations and functions

As outlined in the Terms of Reference (TOR),[5] there are specific roles and expectations associated with the various functions of the advisory group. Failure to adhere to these expectations may lead to early termination of one's membership term, in accordance with the TOR.

3.1. Members

As per the functions of the advisory group, all VCAG members are expected to engage in the review of applicant submissions and to contribute to the advice offered both to the applicants, and to WHO in terms of public health value. This includes participating in relevant pre-meeting calls, participating in discussions during the meeting, contributing to development of the meeting report according to working group allocations, and returning all administrative documentation required for meetings in accordance with the instructions in accompanying communications sent by the VCAG Secretariat. Failure to do so may mean it is not possible to process documents in time, resulting in the member being unable to attend or participate in the meeting. All members are required to complete a WHO DoI form and are subject to confidentiality rules during their tenure as a VCAG member. Full details of the required documentation that a member must submit prior to a meeting are outlined in Section 4, Administrative requirements.

3.1.1. Co-chairs

In addition to the expectations of a VCAG member, VCAG co-chairs accept to take on additional roles for their term as co-chair, including:

- chairing the meetings of VCAG;
- liaising with the WHO Secretariat during and between the meetings;
- facilitating productive and respectful discussions;
- ensuring that the content of the meeting report accurately reflects the outcomes and recommendations derived in the course of the meeting;
- assisting the WHO Secretariat in finalizing the report of each VCAG meeting; and
- participating in meetings of WHO advisory groups in the capacity of an observer, as and when invited by WHO.

3.1.2. Working groups

Working groups are subgroups of VCAG members that have been assigned to perform the in-depth reviews of a particular intervention class. The composition of a working group will normally include experts with a range of diverse expertise, including entomology, epidemiology, biostatistics and modelling, product development and regulation. Efforts will be made to maintain the working group's core composition while the given intervention class remains under review by the

5 VCAG Terms of Reference (https://www.who.int/groups/vector-control-advisory-group/about)

advisory group and VCAG members remain under tenure; however, it may be necessary to evolve the working group's composition over time to enable a stage-appropriate review of submissions, or to address logistical issues (e.g. challenges associated with time zones during the virtual hosting of a meeting). When the tenure of a VCAG member ends, the VCAG Secretariat may assign a new member to the group, either to augment low numbers, as needed, or to supplement expertise.

A working group will normally consist of four or more experts at any given meeting. There is, however, no maximum limit to the number of people in a working group. The WHO VCAG Secretariat will nominate a VCAG member as the lead for each working group. The working group for a given intervention class will be assigned prior to the VCAG meeting (or carried over from previous meetings, where appropriate).

Upon receipt of the full submission from the applicants, working group members are tasked with conducting a technical review of the material and developing feedback. That tentative feedback of the submission will be collated and discussed during a pre-meeting call among working group members and the VCAG Secretariat, normally in the week preceding the meeting. A summary of the call will be developed by a designated rapporteur and shared with the rest of the VCAG members (minus those with an established conflict of interest). This summary is intended to bring the rest of the VCAG members up to speed on the submission and any significant issues or discussion points considered during the call, prior to the meeting.

Following the applicants' presentation and Q&A session in the VCAG meeting itself, working group members will (in a closed discussion without the applicants) share their initial thoughts on the submission and the respective presentation, and lead a discussion with the rest of VCAG. Where observers have been invited as technical experts, their input will be sought at this stage. Preliminary feedback will then be delivered to the applicants following the closed discussion. Depending on the format of the meeting (virtual or in-person), this may be the same day or the following day.

Together, the working group is responsible for writing the section for inclusion in the VCAG meeting report relating to:

- summaries of the applicant submissions, as well as the presentations and discussions that took place during the meeting;
- the guidance provided to the applicants relating to their submission; and
- any formal advice from the advisory group to WHO about the public health value of any evaluated intervention.

A nominated rapporteur will lead the development of the draft, but all members are expected to contribute to reviewing and editing the report. The working group leads are expected to help ensure timely completion of the respective report sections.

3.2. Applicants

Following a call for participation three months prior to a scheduled meeting, applicants who are formally invited to make a submission are expected to do so in accordance with the instructions and timelines indicated in these Standard Operating

Procedures and in all communications received from the Secretariat. Participating in the meeting requires that submissions be complete, coherent, of high quality, and received on time. Applicants will be expected to revise their submissions upon request, without delay, should there be any issues of quality or completeness.

During the meeting, each applicant group is expected to make a presentation to VCAG about their intervention and report on progress of the generation of evidence that will contribute to its evaluation. Applicants are expected to make themselves available for a Q&A session following their presentation. The composition of the applicant team that will present to VCAG during the meeting is at the discretion of the applicant. Nevertheless, applicant representation at the meeting should encompass, as much as possible, the interdisciplinary team involved in the trials: principal investigators, site investigators performing the trials, lead statisticians, and potential or actual manufacturers of the intervention. WHO also actively encourages researchers/developers/manufacturers from the disease-endemic countries (where the trials are being conducted) to present the work. Broad representation at meetings facilitates dialogue between VCAG and the applicants.

For independent researchers engaged by manufacturers to conduct some or all of the required epidemiological studies, it is essential to have participation of the research partner(s) at the meeting, as VCAG's remit and focus is the evaluation of such epidemiological evidence. In cases where researchers lead the submissions for evaluation, manufacturers are also encouraged to be engaged in VCAG meetings from the start of the evaluation process, as it will be their responsibility to continue engagement with the WHO Prequalification Team for Vector Control Products (PQT-VCP) for prequalification of the intervention and its life-cycle management.

During development of the meeting report, applicants will be requested to review the respective sections of the draft report. As stated above, this is to ensure factual accuracy of the meeting interactions and to avoid accidental publication of proprietary information, rather than for applicants to edit or remove specific guidance or advice made by VCAG. The estimated timeline for the meeting report is found in Annex 1.

3.3. Observers

At the discretion of the VCAG Secretariat, WHO may invite technical observers to attend open sessions of VCAG convenings. Observers may be invited to attend the meetings to:

a) provide information, opinion or guidance on a relevant topic (e.g. as a presenter);

b) provide input on the applicant interventions presented to VCAG (e.g. as an ad hoc technical expert);

c) observe the session presentations and related discussions (e.g. as a member of a related WHO advisory group); or

d) represent a commercial or non-commercial entity, nongovernmental or international organization (e.g. an industry representative or collaborator from a UN sister organization).

In all cases, the purpose of the invitation will be made clear to the observer invited to attend the meeting, defined in the communication accompanying the formal invitation letter. An observer may contribute to session discussions at the invitation of the co-chair or session chair only.

Observers, operating in any capacity, do not play a role in developing the final guidance provided to applicants, or advice to WHO on the public health value of evaluated interventions.

Technical experts invited to assist in the review of interventions may be selected by referring to the established roster of experts maintained by the Secretariat, or exceptionally by reaching out to specific individuals with the required expertise. Although potentially drawn from the same roster of experts, participating in a VCAG meeting as an ad hoc technical expert does not lead to VCAG membership. The role of these ad hoc experts is to augment the expertise of VCAG in order to carry out an assessment of the submission(s) and provide technical advice on the public health value of the intervention. The expertise of a previous VCAG member may be requested to complement that of existing members following the completion of their membership term. In such a case, this ad hoc participation as an observer should occur for no more than two meetings.

Observers attending in an individual capacity will be required to complete a DoI form prior to attending the meeting. Meeting attendance will be subject to review and decision by the VCAG Secretariat, in consultation with WHO's Compliance, Risk Management and Ethics team as necessary.

Observers attending as a representative of a governmental institution/ intergovernmental organization, or from a non-state actor organization, will be subject to internal due diligence and risk assessment including conflict of interest considerations in accordance with the Framework of Engagement with Non-State Actors (FENSA), as outlined in the TOR.

All observers, irrespective of the purpose of their invitation, must complete a CoU.

3.4. WHO Secretariat

The WHO VCAG Secretariat will coordinate meetings and related preparatory activities, support VCAG members in the development of the meeting report, and provide scientific, technical and administrative support to VCAG members as needed. The Secretariat will also provide clear communication to applicants about requirements for meetings, submissions and timelines, and respond in a timely manner to any questions from applicants and members relating to the evaluation process.

During the closed sessions of the meeting, participation of WHO staff is restricted to the *essential* VCAG Secretariat only. Open sessions may be attended by affiliated staff and consultants, by invitation.

4. Administrative requirements

Prior to each and every meeting, there are a number of administrative documents that must be duly completed and submitted to the Secretariat before participation in a meeting may be approved.

4.1. Letter of invitation

Leading up to a meeting, VCAG members and observers will receive a letter of invitation stating the requested function of that individual during the meeting. Invitation letters will need to be signed and returned in line with the instructions in the accompanying communication, but no later than six weeks before the meeting date.

For an in-person meeting, the duly signed letter of invitation and the memorandum of agreement (below) are an integral requirement for approving participation in a meeting. It is prohibited for WHO to make travel arrangements for advisory group members for an in-person meeting without these two documents being submitted.

4.2. Memorandum of Agreement (MoA)

The MoA comprises an essential part of the documentation that needs to be returned to the VCAG Secretariat. This must be duly completed as per the accompanying instructions and returned by the requested date, no later than six weeks before the scheduled meeting date.

4.3. Confidentiality Undertaking (CoU)

A COU must be completed and signed by all VCAG members and observers before each meeting. VCAG members may not publicly disclose any documents or information related to the meeting or applicant submissions, or repeat or quote any contents of discussions outside of official VCAG communications.

The WHO VCAG Secretariat will share submitted documents with the assigned working group members and the co-chairs, unless deemed important to seek wider input from the other VCAG members in the early stages of review. All advisors (except where individuals are deemed to have a relevant conflict of interest with that submission) will be part of conversations about the public health value of the intervention; this may require some or all of the documents originally provided to the working group to be shared with the wider group.

Unless documents are already in the public domain (e.g. registered protocols or published manuscripts), any and all information and documentation to which VCAG members are given access while performing VCAG-related activities will be considered confidential. No part(s) of any applicant submission will be published in a VCAG report without the consent of the applicants.

The meeting report will provide a summary of the intervention and a record of VCAG's advice and recommendations to each applicant. As stated above, the relevant section of the draft meeting report will be reviewed by applicants prior to publication to ensure that proprietary information is not shared.

4.4. Declaration of Interest (DoI)

A DoI form must be completed and signed by all VCAG members and observers (acting in an individual capacity) before each meeting. All invitations to a VCAG meeting are subject to conflict of interest determinations. Any conflicts of interest disclosed by VCAG members and observers will be reviewed and managed as deemed appropriate by the Secretariat, in consultation with the WHO Compliance, Risk Management and Ethics team (CRE) as required. All established conflicts of interest and their management will be read out in full at the commencement of the meeting and captured in the meeting report.

Management of any established conflicts of interest may range from the interest being formally acknowledged in the meeting report, to the advisor being excluded from part or all of the meeting for which there is an established conflict, and being denied access to any submitted documents and any reports under development.

More information about disclosure, declarations and management of interests within WHO can be found at: https://www.who.int/about/ethics/declarations-of-interest.

5. Tracking of interventions submitted to VCAG

The WHO VCAG Secretariat maintains a condensed report that tracks interventions that have participated in at least one VCAG meeting. The report, available on the VCAG webpage,[6] collates high-level information about each intervention. The table's interactive format enables users to filter interventions by intervention class, target disease, status of evidence generation, and WHO recommendation (where it exists). While all information contained in the interactive report can be found publicly in published meeting reports, the aggregate report facilitates a broad overview for interested stakeholders and provides links to the relevant documentation and WHO recommendations.

6. Effective date

These revised Standard Operating Procedures are effective as of 1 August 2022. They will be further amended as necessary to ensure consistency of VCAG operations with the ongoing alignment of WHO recommendations and the evaluation procedures.

6 See the VCAG webpage for the link to the summary report: https://www.who.int/groups/vector-control-advisory-group

Annex 1. Process and timeline for typical applicant submissions for VCAG meetings

The timeline for activities leading up to the biannual meetings is calculated based on the established dates of the meeting. Applicants are encouraged to note that there is minimal flexibility in pre-meeting scheduling, due to the need to synchronize other coordination activities.

STEP #	TASK/ACTION	RESPONSIBILITY	COMMENTS	DURATION OF ACTIVITY (APPROX.)	RELATIVE TIMELINE
1	Open call to applicants to determine if they are interested in participating in the meeting	VCAG Secretariat	Email is sent to applicants assigned to the new intervention pathway.		12–14 weeks prior to meeting
2	Expressions of interest received	Applicants VCAG Secretariat	Applicants respond to call; Secretariat reviews subject matter of proposed submissions, and prioritizes (if needed) which groups can be accommodated in the agenda.		10 weeks prior to meeting
3	Individual applicant groups invited to participate in the upcoming meeting	VCAG Secretariat	Secretariat informs applicants of decision, and sends instructions and documents for submission to invited applicants.		Nine weeks prior to meeting
4	Application form and supporting documents submitted to VCAG Secretariat	Applicants	Applicants have three weeks to prepare their submission, which is to be shared with the Secretariat via a link to deposit their documents on a secure cloud server, or by email if necessary.		Six weeks prior to meeting
5	Review of documents by Secretariat Feedback to applicant to make changes, **if needed**	VCAG Secretariat Applicants	VCAG Secretariat checks completeness and quality of the submission. Applicants are to expedite any revisions needed. Documents undergo technical review of content by either the Global Malaria Programme or Department of Control of Neglected Tropical Diseases.	Two weeks	
6	Submissions distributed to relevant VCAG working groups	VCAG Secretariat	Secretariat shares the respective submissions with VCAG members as per their working group composition.		Four weeks prior to meeting
7	Documents reviewed and feedback compiled	Working groups	Working group members review the documents individually and make notes.	~ Three weeks	
8	Teleconferences for each working group	Working groups VCAG Secretariat	Working groups convene in a pre-meeting call to discuss the relevant points identified in individual reviews, and formulate tentative questions, feedback and advice to applicant. Summary document prepared to share with the rest of VCAG.		~ One week prior to meeting

STEP #	TASK/ACTION	RESPONSIBILITY	COMMENTS	DURATION OF ACTIVITY (APPROX.)	RELATIVE TIMELINE
9	VCAG meeting	VCAG Secretariat VCAG members Applicants	Applicant presentations and Q&A session take place with VCAG. VCAG deliberates on guidance to applicants and/or evaluation of public health value (as appropriate for stage of evaluation) in closed discussion. VCAG provides preliminary, provisional feedback to applicants.	VCAG meeting	
10	Draft of meeting report prepared: • VCAG's evaluation of submissions • General meeting report	Working groups VCAG Secretariat	Summaries of the reviews are prepared, conclusions/ recommendations are finalized by working groups. Secretariat drafts general sections of meeting report.	~ One week	
11	Individual components of meeting report reviewed	VCAG Secretariat	Draft texts from working groups are reviewed, checked for compliance with WHO evaluation criteria and recommendations.	~ 1.5 weeks	
12	Applicant review of appropriate draft text of the meeting report	Applicants	Applicants review respective sections of the draft report. The review serves to avoid accidental publication of factual inaccuracies and proprietary information (not to edit or remove specific VCAG recommendations).	~ One week	
13	VCAG review of all sections of draft meeting report	VCAG members	All components of the report are compiled (including any off-cycle reviews from the preceding inter-meeting period, see Annex 2). Individual working groups are to: 1) respond to particular queries raised by the applicants; 2) review the rest of the sections of the meeting report related to other interventions, and general content.	~ One week	
14	Meeting report reviewed and edited	VCAG Secretariat	Meeting report is compiled, reviewed in-house and edited.	~ 1.5 weeks	
15	Meeting report enters production process	WHO Publication team	Meeting report undergoes formal editing, layout and document clearance process for publication.	~ 2.5 weeks	
16	Meeting report published	WHO Publication team VCAG Secretariat	Document is published on the WHO VCAG website and circulated to all participants of the meeting.		2–3 months after meeting

* Note: This timeline is indicative; some of the steps may not be required or may take more or less time than indicated. Publication of the meeting report according to this schedule is dependent upon respective parties' compliance with the requested timeline.

Annex 2. Process and timeline for off-cycle reviews

Once a request has been received for an off-cycle review and the VCAG Secretariat has deemed it to meet the criteria, the applicants then submit their documentation as per the instructions of the Secretariat, and the following steps are taken.

STEP #	TASK	RESPONSIBILITY	COMMENTS	TIMELINE/ DURATION*
1	Applicants request off-cycle review	Applicants	Applicants submit a formal request for off-cycle review with appropriate justifications. No submission is to be made without the request being accepted.	Request must be received at least one week in advance of the anticipated submission date (see considerations outlined in step 4 below).
2	Review of request and justifications	VCAG Secretariat	Secretariat checks availability of working group, assesses criteria for eligibility for off-cycle review.	One week
3	Request for off-cycle review is either accepted or declined	VCAG Secretariat	If accepted, applicants receive invitation and relevant instructions for the submission. Secretariat informs the rest of VCAG that an off-cycle review is taking place. If declined, no further action taken.	
4	Application and supporting documents prepared and submitted	Applicants	Submission is made from the applicants to the Secretariat.	Submission must be more than one month after the conclusion of the previous meeting, and three full months prior to commencement of the next meeting.[7]
5	Review of documents by Secretariat	VCAG Secretariat	VCAG Secretariat checks for completeness of the application. Technical review of content is conducted by the Global Malaria Programme or Department of Control of Neglected Tropical Diseases (as appropriate).	Three days
6	Applicant provides clarifications for submission (if needed)	Applicants		Three days
7	Applicant submissions distributed to VCAG working group	VCAG Secretariat	Completed application is re-checked and shared with the working group.[8]	Two days

7 This is to avoid overlap of workload associated with the development of the meeting report in the month following the previous meeting, and then preparations for the next meeting, which begin three months before it is scheduled.

8 This may be supplemented by a presentation by the applicants, upon request by the Secretariat.

8	Documents reviewed and feedback compiled	Working group	Working group members review the documents individually and make notes, and group lead compiles feedback.	10 days
9	Teleconference for working group, drafting of report	Working group VCAG Secretariat	Working group may be convened to discuss individual concerns or points of interest. The preliminary report is drafted by the working group.	Five days
10	Draft text reviewed by VCAG Secretariat	Working group VCAG Secretariat	Secretariat reviews VCAG advice and provides feedback, if required.	Three days
11	Report circulated to rest of VCAG (for information).	VCAG Secretariat		One day
12	Feedback shared with applicants	Applicants	Applicant review serves to avoid accidental publication of factual inaccuracies or proprietary information (not to edit or remove specific VCAG recommendations).	Three days
13	Draft text revised as necessary, working group consulted for any queries	VCAG Secretariat	Secretariat edits draft as needed, in consultation with working group.	Three days
14	Preliminary report shared with applicants	VCAG Secretariat	Provisional text is finalized, and shared informally with the applicant.[9]	One day
15	Summary presentation provided for VCAG members	Working group	Working group lead provides a short summary of the submission, outcomes of the review, and guidance provided to applicants.	**Next VCAG meeting**
16	Official publication of the review in the next VCAG meeting report	VCAG Secretariat		**As per the report development steps in Annex 1 (step 13 onward)**

* Note: This timeline is indicative; some of the steps may not be required or may take more or less time than indicated. All days refer to standard working days (does not include weekends or public holidays).

9 The text remains subject to final review and agreement by the rest of VCAG, as well as formal editing as per standard publication requirements for WHO publications. As a reminder, official guidance/advice from VCAG comes only in the form of the published meeting report.