WHO prequalification of Vector Control Products

Preparation of entomology study reports

Modules 3 and 5

PURPOSE

This document describes the suggested preparation of entomology reports (laboratory, semi-field, small- and large-scale field, and community studies) for submission to PQT/VCP as part of product dossiers. The purpose of this document is to familiarize prospective applicants and contract research organizations (CROs), who may be generating study reports, with the expected format of study reports, critical methodological and analytical aspects to be reported to PQT/VCP, and presentation of results. This document is a companion piece to the Entomology assessment process AMS document, which provides further details of the assessment process once study reports are received by PQT/VCP, including the data and information that are included in the WHO public assessment report(s) (WHOPAR).

PROCESS

Report preparation

The manufacturer is responsible for generating the necessary data/information for product dossiers and compiling the complete dossier for submission. Product dossiers are compiled from individual study reports that address the identified data requirements for that product type.

Each study report submitted in a dossier must contain a comprehensive description of the study, methods, procedures and results and include justification(s) for specific scientific approaches and/or deviations from standardized methods.

In some cases, a single study report may be prepared to meet the requirements of multiple bodies. In these cases, those aspects of the study report that are not intended for assessment by PQT/VCP should be clearly identified.

All reports must be submitted with 1) an excel file containing the unblinded raw and summarised data from each sub-study in the report and 2) a file containing the code used for statistical analyses in the format that it was produced. Outputs from statistical analysis programmes should be included as an annex to the report.

Report style

Study reports are assessed for compliance with the published WHO guidance. As such, reports should be written such that the requirements addressed by that study are clearly identifiable during the assessment process. Clear, explicit statements in study reports will minimize the number of clarifications that are required during assessment.

Report content and critical study parameters

Study reports submitted to PQT/VCP in product dossiers must contain all aspects of methodologies, and/or justifications for deviations, that have been identified/described in the relevant WHO guidance documents. Results should be reported according to the requirements outlined in implementation guidance documents, using the provided table formats and figure requirements where available.

Report structure

Suggested study report sections for entomology study reports are described in the Annexes. These sections are provided for guidance and can be adapted according to the requirements of the manufacturer and partner CROs. Suggested formats for the presentation of graphical and tabular results are presented in relevant implementation guidance documents.

The critical parameters identified are those parameters which influence the interpretability of results. Additional parameters may be reported depending on the design and intent of the study.

Annexes. Entomology study report sections and critical parameters to report

- Annex I. ITN studies
- Annex II. IRS studies
- Annex III. Larvicide studies
- Annex IV. Space spray studies

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