WHO Prequalification of Vector Control Products

Preparation of supporting statistical files for submission in product dossiers

Purpose

This document provides guidance on the format and compilation of statistical files that are submitted to WHO PQT/VCP in product dossiers as supporting data to quality and efficacy studies.

Advice

The applicant is responsible for preparing and submitting a complete dossier including the required data and information to support the specific application. Within product dossiers, raw data and statistical files are submitted to support the evidence presented in individual quality and efficacy study reports. The following guidance has been developed to facilitate consistency in the preparation of applications and to increase efficiency in application screening and product assessment processes.

Disciplines requiring the submission of statistical files

The submission of supporting statistical files is required for certain quality and efficacy studies. Separate files should be submitted for each discipline.

Studies requiring the submission of statistical files

The studies listed in Table 1 require the submission of raw data and statistical files. Note that the insecticide resistance characterization is not usually submitted as a standalone study, but as a component of a larger study, e.g. a semi-field study. It has been presented as a separate study within this document for the purpose of providing clarity regarding the applicable supporting statistical files.

Table 1. Studies requiring the submission of supporting statistical files in product dossiers

Product type	Study
Insecticide-treated nets (ITNs)	Baseline quality check
	Insecticide resistance characterization[1]
	Regeneration study
	Wash resistance
	Semi-field (experimental hut, Ifakara ambient chamber test)
	Long-term community studies
Indoor residual sprays	Laboratory residual efficacy
	Insecticide resistance characterization[1]
	Semi-field (experimental hut)
Larvicides	Insecticide resistance characterization[1]
	Simulated semi-field
	Studies in natural breeding sites
Space sprays	Insecticide resistance characterization[1]
	Indoor/outdoor efficacy
Spatial emanators	Insecticide resistance characterization[1]
	Free-flight room
	Semi-field (experimental hut)

1 Sample size/power calculation files are not required for insecticide resistance characterization as these procedures are defined in the Manual for monitoring insecticide resistance in mosquito vectors and selecting appropriate interventions (https://www.who.int/publications/i/item/9789240051089).

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Raw data

Raw data should be submitted in Excel format. One raw data spreadsheet (Excel workbook) containing all the relevant data (treatments, test systems) in the same worksheet (tab) should be submitted per study. A data dictionary (or similar unblinding of data) should be presented in a separate worksheet within the workbook.

At minimum, a dataset presented in an Excel workbook should contain all the variables analyzed in the corresponding study report. All entries in the workbook should be complete; in cases of missing data, the reason(s) for this should be described and justified in the corresponding study report. Data for a variable should be in the same format throughout the workbook (for example, values for a date variable should be entered in the same format, a numerical variable should have numerical values only, a categorical/factor variable should have either numbers or non-numerical values but not both). The variables in the dataset should be consistent with the corresponding software code files, or the code used to rename/relabel variables should be incorporated into the submitted code.

Templates for raw data are included as annexes to this document.

Statistical files

Code files

For each study, the software codes used for sample size/power calculations and data analyses (descriptive and inferential analyses) should be shared as separate files in the applicable statistical software (for example, R, Stata) or script editor format (Table 2). Prior to submission, all codes should be checked to ensure that they run smoothly with the submitted dataset or function/macro, without any errors.

Code files for sample size/power analysis

When a standard sample size formula/function/package is used, all the parameters and the associated estimates considered should be explicitly stated in the code. For simulations, the code provided should match the steps described in the corresponding study report (data generation, seed, distributions for the outcome and other parameters, estimates for each parameter, fitted model, how the power was generated, etc.). Use annotations to describe each step of the simulations in the code.

When non-standard functions/macros or the software-specific equivalent are used, a full description (purpose, parameters, etc.) should be provided in the code file. In cases where an online power analysis tool has been used, a link should be provided in the corresponding study report.

The variable labels within the code file should be consistent with the variable labels within the corresponding raw data spreadsheet. If variables were renamed or relabeled for analysis, the code for this should be included in the code file and clearly annotated.

Codes for descriptive and inferential data analyses

Submitted statistical codes should be clearly annotated to explicitly describe the analysis that is performed in each section. This should include: the study name; outcome; any data manipulation that is conducted, for example, renaming and/or recoding variables, transforming datasets; the category being analyzed, for example, unwashed/20x washed/pooled, where applicable; comparison group, for example, active or standard comparator, where applicable, and the fitted model (for example, logistic, negative binomial regression, etc.).

When non-standard functions/macros or the software-specific equivalent of the software are used, a full description (purpose, parameters, etc.) should be provided in the code file.

The variable labels within the code file should be consistent with the variable labels within the corresponding raw data spreadsheet. If variables were renamed or relabeled for analysis, the code for this should be included in the code file and clearly annotated.

Analysis log file

The analysis log file includes the entirety of the analysis codes/commands and associated outputs. Analysis logs should be submitted as PDF files.

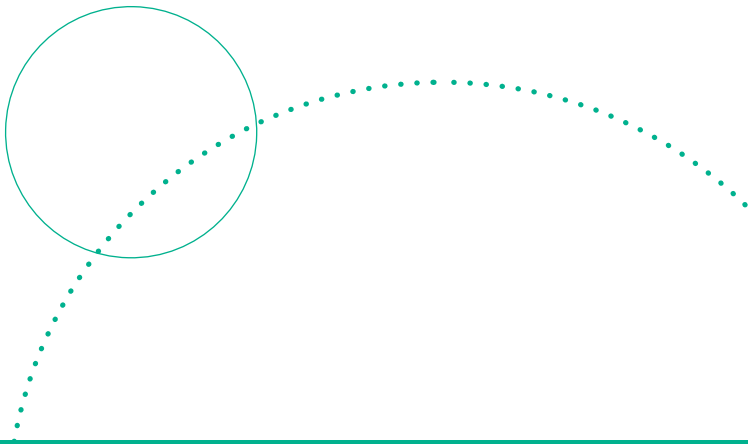

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Table 2. Summary of statistical files to be submitted as supporting documents within product dossiers.

Description	File type	File format	Notes
Study data	Raw data	Excel	One raw data file per study. All datasets (all treatments, all test systems) contained in the same worksheet within the workbook. Include data dictionary for all variables and data codes as a separate Excel worksheet in the same workbook as the raw data.
Sample size/power calculation	Code file*	Text file (PDF not acceptable) or statistical software format	One file per study
	Output file	PDF	One file per study
Descriptive and inferential analyses	Code file*	Text file (PDF not acceptable) or statistical software format	One file for both descriptive and inferential analyses per study. Code should be clearly annotated. All non-standard functions to be fully described.
Analysis log file	Analysis codes and associated outputs	PDF	One file per study.

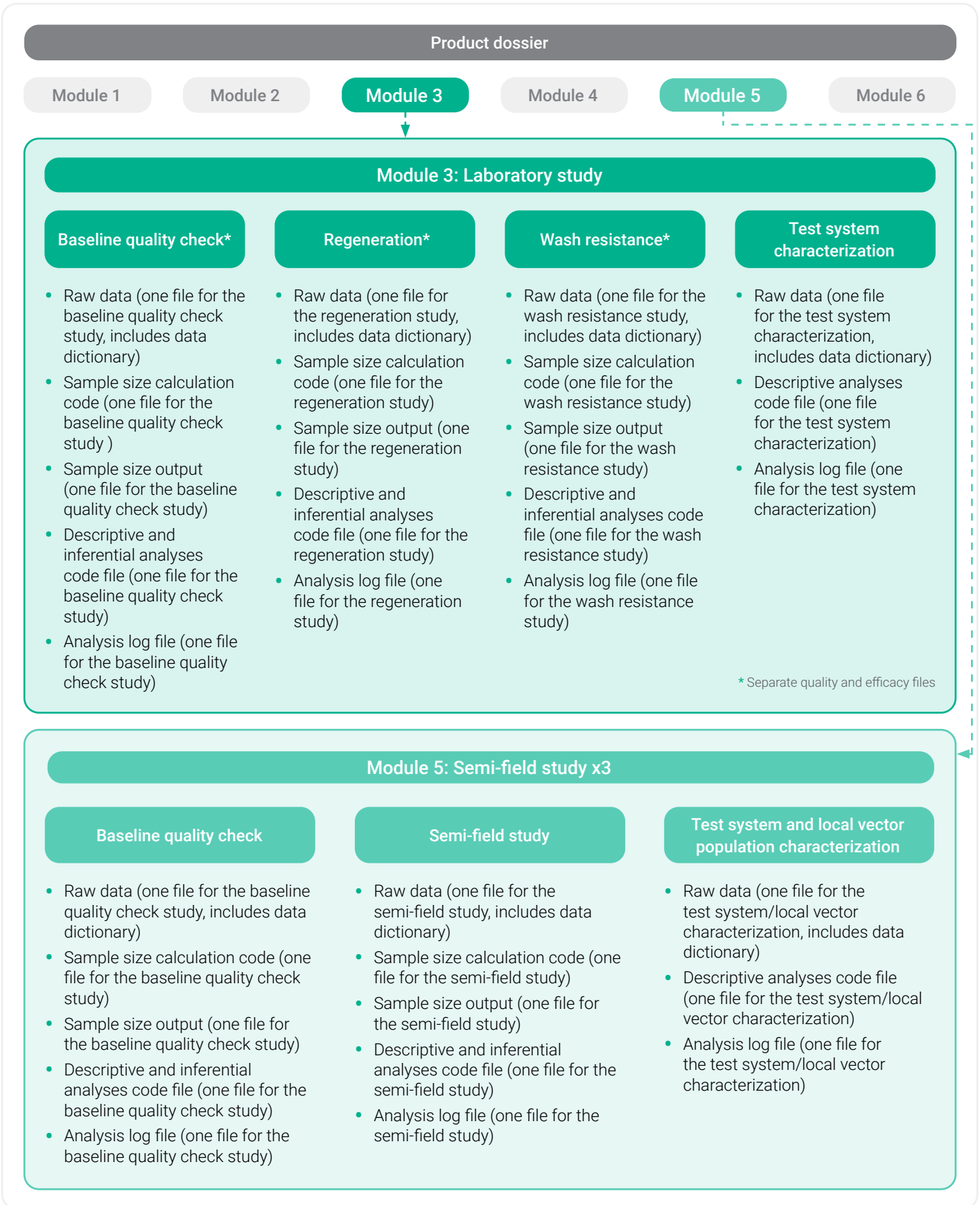
*Prior to submission, all codes should be checked to ensure that they run smoothly with the submitted dataset or function/macro, without any errors.

Example of supporting statistical files to submit within a product dossier

Figure 1 shows an example of an ITN product dossier. In this example, supporting statistical files are required for studies included in both modules 3 and 5. The supporting statistical files to be submitted for each study are listed next to the title of the study.

Note that, for the purpose of providing clarity regarding the applicable supporting statistical files, the insecticide resistance characterization is presented as a separate study. The long-term community studies are not presented separately in the figure because the supporting statistical files are aligned with those for a semi-field study.

Figure 1. Example of the supporting statistical files to be submitted within an ITN product dossier.



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