Global **Malaria** Programme

Data requirements and protocol for determining non-inferiority of insecticide-treated net and indoor residual spraying products within an established WHO intervention class

World Health Organization

This document was updated in May 2019 following an open review process. Please consult the website for any content updates (http://www.who.int/malaria)

Global **Malaria** Programme

Data requirements and protocol for determining non-inferiority of insecticide-treated net and indoor residual spraying products within an established WHO intervention class

World Health Organization

WHO/CDS/GMP/2018.22.Rev.1.

Suggested citation. Data requirements and protocol for determining non-inferiority of insecticide-treated net and indoor residual spraying products within an established WHO intervention class. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Table of contents

ABBREVIATIONS

AI	active ingredient
CI	confidence interval
GLM	generalized linear model
GMP	Global Malaria Programme
IRB	Institutional Review Board
IRS	indoor residual spraying
ITN	insecticide-treated net
LSD	Latin square design
M	meter
MPAC	Malaria Policy Advisory Group
OR	odds ratio
PQT	Prequalification Team
VCAG	Vector Control Advisory Group
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

GLOSSARY

active comparator	The active comparator for the non-inferiority trial should be the first-in-class product that demonstrated its public health value by means of cluster randomized controlled trials with epidemiological endpoints. *Note: second in class products that have demonstrated non-inferiority to first in class products may then be used as active comparators for non-inferiority testing of other second-in-class products.*
blood-feeding rate	The proportion of blood-fed female mosquitoes relative to the total number of female mosquitoes found in an experimental hut.
candidate product	A novel product that is thought to have the same entomological effect as a product in an established intervention class, but has not yet provided the entomological evidence to join the class (in order to become a second-in-class product).
control	An untreated net or, in the case of indoor residual spraying (IRS), spray of untreated water (water control) that is used to monitor the quality of the evaluation by ensuring that the mortality observed is due to the insecticide active ingredient(s) and not to poor execution of the study (e.g., induced mortality from poor handling of mosquitoes).
current standard of care	The type of insecticide-treated net (ITN) or IRS product predominantly used by the national malaria control programme in the country where the study will be implemented.
deterrence	The reduction in the number of mosquitoes entering an experimental hut with an intervention relative to a control hut.
entomological effect	Entomological effect refers to a product's effect on a disease vector in terms of killing, deterring and reducing fertility, biting rates or susceptibility to infection. Products with different biochemical modes of action may have similar entomological effects on target insects; for example, IRS formulations with pyrethroids and carbamates differ in their biochemical modes of action, yet are considered to have a similar impact on the target insect in areas of insecticide susceptibility.
exophily	The proportion of female mosquitoes in exit traps compared to the sum of the number collected in the hut and exit traps.