

WHO Prequalification of Vector Control Products

Data requirements table – Module 5

DR Code	Requirement	Description/Notes	Method ¹ /reference	Form/template	Number of batches to test
5.0	Module 5 index	Identification of supporting information included within Module 5 to address the data requirements.		<ul style="list-style-type: none"> • Template Module 5 index 	
5.1	Entomological efficacy – semi-field studies	<p>Semi-field studies measure the entomological efficacy of whole ITNs against free-flying vector populations.</p> <p>A minimum of three semi-field studies, of which two must be open system, must be submitted in product dossiers.</p> <p>Batches tested in semi-field studies must be batches that have full characterization provided in Module 3.</p> <p>Semi-field studies must be submitted with accompanying supplementary bioassay data that characterizes the consistency of the fabric of the insecticide-treated nets (ITNs) that were used in the semi-field studies.</p>	<p>Implementation guidance (IG) – Semi-field studies</p> <p>IG – Experimental hut</p> <p>IG – IACT</p> <p>IG – Cone test</p> <p>IG – Tunnel test</p> <p>IG – Control selection</p> <p>IG – Thresholds</p> <p>IG – Novel bioassays</p>		3
5.1.2	Declaration of strains	Declaration of vector strains used in semi-field studies supplementary bioassays.	<p>IG – Strain selection</p> <p>IG – Matrix of Selected Mosquito Strains (MSMS)</p>	<ul style="list-style-type: none"> • Template MSMS 	

¹ Methods identified should be used for the generation of data. Additional and/or alternative methods may be proposed by applicants provided that complete description of the method and validation is included.

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5.2	Long-term community studies	Community studies measure the effectiveness of whole ITNs under conditions of routine use over the intended useful life of the product. A minimum of three long term community studies in diverse geographic regions must be submitted either in product dossiers, or as a post-prequalification commitment.	IG – Community studies		3
5.2.1	Declaration of strains	Declaration of vector strains used in long-term community studies supplementary bioassays and entomological efficacy assessments.	IG – Strain selection	<ul style="list-style-type: none"> • Template MSMS 	
5.3	Other related information	To be proposed by applicant as necessary.			