

Generic Field Evaluation Checklist for PQS Reviewers



When the WHO PQS requires a product to undergo a third party field evaluation a review team will be assembled to assess the proposed field evaluation and later evaluate the final report. This checklist is intended only to aid reviewers and is not part of the field evaluation. It can be used for reviewing both the field evaluation proposal review and final report review.

The field evaluation is to be conducted by a third party implementing partner on behalf of the product manufacturer. The aim of the field evaluation is to ensure that devices and/or technologies perform according to their PQS prequalification specifications when used in field settings, are acceptable to end-users, and have no significant negative impacts on the health system. Optionally it is desirable to include an estimate total life costs or identify key factors impacting life time costs.

1.	Field Evaluation Review (use for either proposed study or final report):		
1.1	Proposal or Final Report		
1.2	Manufacturer		
1.3.1	Equipment details	Model	
1.3.2		Description	
1.3.3		PQS number	
1.3.4		PQS status	
1.3.5		Other info	
1.4.1	Contact details:	Name	
1.4.2	Manufacturer	Email	
1.4.3		Landline	
1.4.4		Cellphone	
1.5.1	Contact details:	Name	
1.5.2	Implementing partner (required)	Email	
1.5.3		Landline	
1.5.4		Cellphone	
1.6.1	PQS requirements and approvals	Field Study Application	
1.6.2		Field Study Protocol	

1.6.3		Implementing partner	
1.6.4		Country review and approval	

2.	Field Evaluation Design, Methodology, Roles and Responsibilities, Objectives and Key Research Questions:	
	Do these address PQS interests and will they lead to PQS pass/fail determinations?	
2.1	Objective 1 (describe)	
2.2	Objective 2 (optional)	
2.3	Objective 3 (optional)	
2.4	Research question 1	
2.5	Research question 2 (optional)	
2.6	Methodology	
2.7	Roles and responsibilities	
2.8	Conflict of interest?	
2.9	Closeout	
2.10	Other	

3.	Performance:	
	Does the field evaluation sufficiently address these categories?	
3.1	Quantity of products	
3.2	Time/seasons	
3.3	Use case(s)	
3.4	Challenges	
3.5	Data collection	
3.6	Data analysis	
3.7	Data presentation	

3.8	Logistics	
3.9	User acceptance	
3.10	Immunization system impacts	
3.11	Other	

4.	Acceptability:	
	Are we able to assess product acceptability via this field evaluation?	
4.1	Health facility worker	<input type="checkbox"/> Equipment <input type="checkbox"/> Operations <input type="checkbox"/> Maintenance <input type="checkbox"/> Training
4.2	Technician	<input type="checkbox"/> Equipment <input type="checkbox"/> Operations <input type="checkbox"/> Maintenance <input type="checkbox"/> Other
4.3	Manager/administrator	<input type="checkbox"/> Equipment <input type="checkbox"/> Operations <input type="checkbox"/> Maintenance <input type="checkbox"/> Training
4.4	Others	<input type="checkbox"/> Equipment <input type="checkbox"/> Operations <input type="checkbox"/> Maintenance <input type="checkbox"/> Training

5.	Impact on Immunization and Health System:	
	Are we able to assess product impacts on the health system via this evaluation?	
5.1	Health facility worker	<input type="checkbox"/> Work load <input type="checkbox"/> Facility operations

		<input type="checkbox"/> Patients <input type="checkbox"/> Planning
5.2	Technician	<input type="checkbox"/> Work load <input type="checkbox"/> Facility operations <input type="checkbox"/> Patients <input type="checkbox"/> Planning
5.3	Manager/administrator	<input type="checkbox"/> Work load <input type="checkbox"/> Facility operations <input type="checkbox"/> Patients <input type="checkbox"/> Planning
5.4	Immunization and Health System	<input type="checkbox"/> Work load <input type="checkbox"/> Facility operations <input type="checkbox"/> Patients <input type="checkbox"/> Planning <input type="checkbox"/> Service delivery <input type="checkbox"/> Other

NOTES:

Reviewer Name

Date