



PB-SAM STUDY CONCLUSION

To be completed after Day 60 follow up, following death of child, or withdrawal from study

1. Date of most recent study visit attended or telephone call confirming vital status or date of death if died or date if withdrawal	Date: ___ / ___ / ___ <i>D D / M M / Y Y Y Y</i>
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2.	Did the participant remain in follow up to day 60?	<input type="checkbox"/> YES <input type="checkbox"/> NO
2.1.	If the answer is NO, state the reason	
	i). Untraceable, unable to establish vital status: Loss to follow up <i>(Select one)</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO
	ii). Died <i>(Select one)</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO
	a. If died, where? <i>(Select one)</i>	<input type="checkbox"/> Not applicable (alive) <input type="checkbox"/> Study hospital <input type="checkbox"/> Community <input type="checkbox"/> Other hospital / Health center <input type="checkbox"/> Unknown
	b. If died, verbal autopsy complete? <i>(Select one)</i>	<input type="checkbox"/> Not applicable (alive) <input type="checkbox"/> YES <input type="checkbox"/> NO
	iii). Protocol withdrawal	<input type="checkbox"/> YES <input type="checkbox"/> NO <i>If checked yes Complete (a) below</i>
	a. Reason for protocol withdrawal	<input type="checkbox"/> SAE <input type="checkbox"/> protocol violation
	iv). Voluntary withdrawal	<input type="checkbox"/> YES <input type="checkbox"/> NO <i>Complete (a) below</i>
	a. Reason given in discussion (tick each mentioned; do not probe for each)	<input type="checkbox"/> Prefer not to say <input type="checkbox"/> Concerned about effect of study medication <input type="checkbox"/> Blood sampling <input type="checkbox"/> Insufficient benefit to participant <input type="checkbox"/> Time/disruption in follow-up visits <input type="checkbox"/> Travel out of research area <input type="checkbox"/> Unable to arrange care for other children <input type="checkbox"/> Others household/community not happy to continue

PB-SAM CONCLUSION FORM v1
PB-SAM [1][0][0][0][2] [][][]



	<input type="checkbox"/> Unsure/unsupportive of reasons for research or of the institution conducting it <input type="checkbox"/> Other _____
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3. Where vital status confirmed? <i>(Select one)</i>	<input type="checkbox"/> Study Clinic Visit <input type="checkbox"/> Community <input type="checkbox"/> Phone
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4. CRF Completed by (Initials) _____	Date: ____ / ____ / ____ <i>DD / MM / YY YY</i>
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