



Patient Initials [ ][ ] [ ][ ]

PB-SAM [1][0] [ ][ ] [ ][ ]

**PB-SAM STUDY CONCLUSION**

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

<b>1. Date of most recent study visit attended or telephone call confirming vital status or date of death if died or date if withdrawal</b>		Date: <u>  </u> / <u>  </u> / <u>  </u> <u>  </u> <u>  </u> <u>  </u> <u>  </u> <i>D D / M M / Y Y Y Y</i>
<b>2.</b>	<b>Did the participant remain in follow up to day 60?</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>2.1.</b>	<b>If the answer is NO, state the reason</b>	
	<b>i).</b> Untraceable, unable to establish vital status: Loss to follow up	<input type="checkbox"/> YES <input type="checkbox"/> NO
	<b>ii).</b> Died <i>(if No, skip to iii.)</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO
	<b>a.</b> If died, where? <i>(Select one)</i>	<input type="checkbox"/> Study hospital <input type="checkbox"/> Community <input type="checkbox"/> Other hospital / Health center <input type="checkbox"/> Unknown
	<b>iii).</b> Protocol withdrawal <i>(if No, skip to iv).</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO <i>If checked yes Complete (a) below</i>
	<b>a.</b> Reason for protocol withdrawal	<input type="checkbox"/> SAE <input type="checkbox"/> protocol violation
	<b>iv).</b> Voluntary withdrawal	<input type="checkbox"/> YES <input type="checkbox"/> NO <i>Complete (a) below</i>
	<b>a.</b> 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 v1.1

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	<input type="checkbox"/> Unsure/unsupportive of reasons for research or of the institution conducting it <input type="checkbox"/> Other _____
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<b>3. Where vital status confirmed?</b> <i>(Select one)</i>	<input type="checkbox"/> Study Hospital <input type="checkbox"/> Study Clinic Visit <input type="checkbox"/> Community <input type="checkbox"/> Phone
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<b>4. CRF Completed by (Initials)</b> _ _ _ _	Date: _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
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<b>5. CRF Verified by (Initials)</b> _ _ _ _	Date: _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
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