

 <p style="font-size: 8px; margin-top: 5px;">Biomarker-guided antibiotic duration for sepsis</p>	<h2 style="margin: 0;">Protocol Non-compliances</h2>
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Participant Trial number:	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
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Any Protocol non-compliances to report?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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EVENT DETAILS:
(Include full details of the non-compliance i.e. exact nature of the event, how and when you became aware, what investigations were undertaken, the implications of the findings, how this event has impacted (or had the potential to impact) either patient safety and/or scientific quality/data credibility, the root cause of the finding)

Date of event: - -

[Insert text]

CORRECTIVE ACTIONS:
(Give details of what immediate corrective action(s) were taken to rectify the situation and minimise the impact of the finding. Consider person responsible, who will be involved, stipulate timelines, consider impact on other areas, additional approvals needed)

[Insert text]

PREVENTATIVE ACTIONS:
(Give details of what actions will be/have been implemented to ensure the event does not happen again. Ensure actions relate to root cause. Consider if Quality Assurance procedures require updating, person responsible, who will be involved. Stipulate timelines, ensure actions are measurable)

[Insert text]

FORM COMPLETED BY:	
Name (please print):	Date: <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
Signature:	

WCTU USE ONLY

ASSESSMENT OF REPORT:			
Date CTU study team aware of event	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>		
Flagged to CI?	Yes <input type="checkbox"/>	Date: <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	No <input type="checkbox"/>
Reviewed by the TMG?	Yes <input type="checkbox"/>	Date: <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> - <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	No <input type="checkbox"/>

COMMENTS:

(Give details of justification for the outcome decision, further recommendations)

[Insert text]

OUTCOME [select one only]:

Not a Deviation/Violation ⇒ Append relevant communications, file in TMF

Deviation ⇒ Append relevant communications, file in TMF
⇒ Date reported to other bodies*:

Violation ⇒ Append relevant communications
⇒ Date forwarded to sponsor's office:
⇒ Date reported to other bodies*:

Serious Breach ⇒ Append relevant communications

⇒ Date breach confirmed (Day 0):

⇒ Date forwarded to MHRA:

⇒ Date forwarded to REC:

⇒ Date forwarded to sponsor's office:

⇒ Date referred to DMC/TSC:

⇒ Date reported to funder:

⇒ Date reported to other bodies*:

*Provide details of other bodies notified (e.g. PI at relevant site, DMC, TSC):

[Insert text]

If deemed necessary by the TMG, has information been forwarded to other study sites for their information?

Yes Date No

Resolution date:

FORM COMPLETED BY:

Name (please print):		Date:	<input type="text" value="dd-mm-yyyy"/>
Signature:			<input type="text" value="dd-mm-yyyy"/>

