

**TABLE LISTING TIMELINES AND PROCEDURE FOR REPORTING SERIOUS ADVERSE EVENTS / ADVERSE EVENTS (SAE/AE)**

<b>Severity:</b>	<b>Nature:</b>	<b>Causality:</b>	<b>PI notifying/ reporting requirements:</b>	<b>Form to use:</b>
<b>Local SAE – resulting in death</b>	Unexpected / Expected	Regardless of causality	Notify (including CMB of the institution*) via fax/email within 24 hours. Full report within 7 calendar days.	<a href="#">SAE Reporting Form</a> for both initial notification and full report
<b>Local SAE – life-threatening</b>	Unexpected / Expected	Regardless of causality	Notify as soon as possible but not later than 7 calendar days. Full report within 8 additional calendar days.	<a href="#">SAE Reporting Form</a> for both initial notification and full report
<b>Local SAE – not life-threatening</b>	Unexpected	Definitely / probably / possibly related	Notify as soon as possible but not later than 15 calendar days.	<a href="#">SAE Reporting Form</a>
<b>Local SAE – not life-threatening</b>	Unexpected	Unlikely / Not related	Provide summary annually. (together with Study Status Report).	
<b>Local SAE – not life-threatening</b>	Expected <b>but</b> there is increase in the rate of occurrence which is judged to be clinically important	Definitely / probably / possibly related	Full report within 15 calendar days.	<a href="#">SAE Reporting Form</a>
<b>Local SAE – not life-threatening</b>	Expected	Definitely / probably / possibly related	Provide summary annually. (together with Study Status Report).	
<b>Non-local SAE – fatal or life threatening</b>	Unexpected	Definitely / probably / possibly related	Full report within 30 calendar days.	<a href="#">Available format (e.g. CIOMS)</a>
<b>Local AE</b>	Unexpected	Definitely / probably / possibly related	Provide summary at the end of the study.	

\* If stipulated by the institution

**[All reporting time lines are counted from the day that the PI becomes aware of the event]**