# University of Leicester Sponsored Multi Centre CTIMP
## Serious Adverse Event Listing Table

<table>
<thead>
<tr>
<th>Sponsor Number</th>
<th>Chief Investigator</th>
<th>Date of Report DD/MM/YYYY</th>
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<tbody>
<tr>
<td>Study Title</td>
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<thead>
<tr>
<th>1 Study Centre</th>
<th>2 Date of SAE</th>
<th>3 Type of Report 1-4</th>
<th>4 Subject Study ID</th>
<th>5 Brief Description of Event</th>
<th>6 Serious Criteria 1-6</th>
<th>7 Causality Related/unrelated</th>
<th>8 Expectedness Expected/unexpected</th>
<th>9 Outcome 1-5</th>
<th>10 Date of Resolution</th>
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Chief Investigator Name ------------------------------- Signature ------------------------------- Date-------------------------

All SAEs that are not resolved at time of SAE line listing submission must be included on subsequent line listings until resolution confirmed.

Appendix 6 to SOP S-1009 Multi Centre CTIMP Serious Adverse Event Listing Table Version 1 December 2016
CTIMP Line Listing Guidance

1. Study site: list site name/number - If numbers utilised ensure that the Sponsor is provided with a listing of corresponding site names.
2. Date of SAE: Provide date of SAE
3. Type of report: List relevant number in column
   1 – Initial
   2 - Follow up
   3 - Final
   4 - Initial and Final
4. Subject Study ID: Provide details of subject's unique study Identification Number. Note: No personal identifiable data must be used.
5. Brief description of event: Provide brief description of event and subsequent investigations/actions
6. Serious Criteria: List relevant number in column
   1 - Resulted in Death
   2 - Life Threatening
   3 - In-patient Hospitalisation/prolongation of existing hospitalisation
   4 - Persistent or significant disability/incapacity
   5 - Congenital anomaly/birth defect
   6 - Other
7. Causality: record Related or Unrelated
8. Expectedness: record Expected or Unexpected

Where an event is related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and requires expedited reporting - Inform the Sponsor Immediately.

9. Outcome of event
   1 - Resolved
   2 - Resolved with Sequelae
   3 - Ongoing
   4 - Unknown at Present
   5 - Fatal
Where an event is Fatal, the Sponsor will require further information with regards to cause of death.

10. Date of resolution: All SAES must be followed up until resolution