UNIVERSITY OF LEICESTER

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

Sponsor Number		**Chief Investigator**	**Date of Report DD/MM/YYYY**
Study Title			

1 Study Centre	2 Date of SAE	3 Type of Report 1-4	4 Subject Study ID	5 Brief Description of Event	6 Serious Criteria 1-6	7 Causality Related/ unrelated	8 Expectedness Expected/ unexpected	9 Outcome 1-5	10 Date of Resolution

Chief Investigator Name ---------- Signature ---------- Date----------

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

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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