UNIVERSITY OF LEICESTER

Information requested	Response
Sponsor reference number	
Study title or acronym	

UoL sponsored multi-centre CTIMP serious adverse event line listing table

1 Study Centre	2 Subject Study ID	3 Date of SAE (dd/mm/yyyy)	4 Date study team aware (dd/mm/yyyy)	5 Type of report (1-4)†	6 Title of event	7 Serious Criteria (1-6)*	8 Causality Related/ unrelated	9 Expectedness Expected/ Unexpected (As per RSI)	10 Outcome (1-5)‡	11 Date of Resolution (dd/mm/yyyy)

Any SAEs that are not completed at time of SAE line listing submission must be included on subsequent line listings until completion is confirmed.

Information Requested	Response
Chief Investigator Name	
Date	
Signature	

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CTIMP Line Listing Guidance

1. Study centre: List site name/number - If numbers utilised ensure that the Sponsor is provided with a listing of corresponding site names.
2. Subject Study ID: Provide details of subject's unique study Identification Number. Note: No personal identifiable data must be used.
3. Date of SAE: Provide date of SAE
4. Date study team aware: provide the date the study team were made aware of the SAE
5. Type of report: List relevant number in column
    a. 1 – Initial
    b. 2 - Follow up
    c. 3 - Final
    d. 4 - Initial and Final
6. Title of event: List the name of the event
7. Serious Criteria: List relevant number in column
    a. 1 - Resulted in Death
    b. 2 - Life Threatening
    c. 3 - In-patient Hospitalisation/prolongation of existing hospitalisation
    d. 4 - Persistent or significant disability/incapacity
    e. 5 - Congenital anomaly/birth defect
    f. 6 – Other
8. Causality: State whether the event was related or unrelated
9. 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.**)
10. Outcome of event: List relevant number in column;
    a. 1 - Resolved
    b. 2 - Resolved with Sequelae
    c. 3 - Ongoing
    d. 4 - Unknown at Present
    e. 5 – Fatal (Where an event is Fatal, the Sponsor will require further information with regards to cause of death.)
11. Date of resolution: List the date the event was considered completed i.e. the date when all the information relating to this event has been captured and there will be no further information to obtain. All SAES (excluding fatalities) must be followed up until resolution or until the condition has stabilised with no further change expected.