Adverse Event Reporting Form

1. What are you reporting? □ AE □ AR □ SAR □ SAE □ SSAR □ SARI □ SUSAR

2. Report type □ Initial report □ Follow up report

3. Principal Investigator

4. REC / R&D reference numbers

5. Date of SAE onset (dd/mm/yy) / /

6. Time of onset (hh:mm)

7. Criteria for Definition of SAE

   □ Death of patient
   □ Inpatient/prolongation hospitalisation
   □ Congenital anomaly or birth defect
   □ Life threatening
   □ Persistent or significant disability

7. Narrative of Event/Reaction: (Please provide account of event, similar to that of discharge summary, please mention e.g.: body site, signs & symptoms, severity, treatment of event, concurrent treatment, other relevant medical history, relevant lab or diagnostic results)

8. In the Investigator’s opinion was the event related to the IMP/device?

   □ Definitely □ Probably □ Possibly □ Unlikely □ Not related

9. Action taken with study IMP/device

   □ None □ Dose reduced □ Dose reduced temporarily
   □ Discontinued temporarily □ Discontinued permanently □ Patient withdrawn

10. If related to IMP/device was this reaction unexpected?

    (Suspected Unexpected Serious Adverse Reaction – SUSAR)

    □ Yes □ No □ Not applicable
11. Did event/reaction abate after stopping IMP/device?
   ☐ Yes  ☐ No  ☐ Not applicable

12. IMP/device and concomitant medication information

<table>
<thead>
<tr>
<th>IMP/Device Details</th>
<th>Start date (dd/mm/yy)</th>
<th>Dose prior to SAE (dd/mm/yy)</th>
<th>Route(s) of administration</th>
<th>Indication</th>
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13. What was the outcome of the SAE?
   ☐ Recovered  ☐ Recovered with sequelae  ☐ Continuing
   ☐ Patient died  ☐ Unknown

14. Date event resolved: (dd/mm/yy)
    /  /  

15. Date patient died: (dd/mm/yy)
    /  /  /

16. Cause of death obtained from (if patient died):
   ☐ Coroner’s inquest  ☐ Death certificate  ☐ Working diagnosis

Contact details

17. Contact person for further information:
____________________________________________________________________________________

18. Telephone number: __________________________  19. Email address: __________________________
____________________________________________________________________________________

Signatures

Person completing report
(Please print) __________________________ Date __________________________ Signature __________________________

Principal Investigator
(Please print) (if not completing report) __________________________ Date __________________________ Signature __________________________