# COPE-COMPARE: Serious Adverse Event

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**Trial ID:** WP4

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| Did the adverse event lead to death | □ Yes □ No |
| Did it result in a life-threatening illness or injury | □ Yes □ No |
| Did it result in a permanent impairment of a body structure or a body function | □ Yes □ No |
| Did it require hospitalisation? | □ Yes □ No |
| Did it require prolongation of hospitalisation? | □ Yes □ No |
| Did it result in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function | □ Yes □ No |

If **all** these questions are answered with **No**, then only complete the Adverse Events List.

If at least **1** question is answered with **Yes**, please continue below.

|  |  |
| --- | --- |
| Date of Onset of Adverse Event | dd /mm / yyyy |
| Is event still ongoing? Y/N | □ Yes □ No |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Q1 | | Please describe the event | | | |
|  | | | | | |
| Q2 | | Action Taken | | | |
|  | | | | | |
| Q3 | | Outcome: | | | |
|  | | | | | |
| Q5 | If the patient is alive, please provide further details: | | | | |
|  | Did the event result in incapacity/inability to work? | | | □ Yes □ No | |
|  | Did the event result in a sign/symptom that interferes with the subject’s usual activity? | | | □ Yes □ No | |
|  | Did the event cause signs/symptoms that resolved with no sequelae? | | | □ Yes □ No | |
|  | Did the event arise from device deficiency? | | | □ Yes □ No | |
|  | Did the event arise from device user error? | | | □ Yes □ No | |
|  | Did the event result in a life-threatening illness or injury? | | | □ Yes □ No | |
|  | Did the event result in permanent impairment of a body structure or a body function? | | | □ Yes □ No | |
|  | Did the event require prolongation of hospitalisation? | | | □ Yes □ No | |
|  | Did the event result in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function? | | | □ Yes □ No | |
| Q6 | Did the event require **rehospitalisation**?  If **Yes**, please provide the following information: | | | □ Yes □ No | |
|  | Date of Admission | | | dd /mm / yyyy | |
|  | Date of Discharge | | | dd /mm / yyyy | |
|  | Was the patient admitted to ICU | | | □ Yes □ No | |
|  | Was dialysis needed | | | □ Yes □ No | |
|  | Was a kidney biopsy taken | | | □ Yes □ No | |
|  | Was surgery required | | | □ Yes □ No | |
|  | Comments: | | | | |
| Q7 | Did the event led to **death?**  If **Yes**, please provide the following information: | | | □ Yes □ No |
|  | Date of death: | | dd /mm / yyyy | |
|  | Treatment related Y/N/Unknown | | □ Yes □ No □ Unknown | |
|  | Cause of Death (tick all that apply)  □ Cerebrovascular Accident  □ Multi Organ Failure □ Pneumonia  □ Sepsis  □ Transplant related  □ Other | | | |
|  | If other please give details: | | | |

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| --- | --- |
| Please give contact details of someone who can provide more information: | |
| Contact Name: |  |
| Contact Phone: |  |
| Contact Email: |  |

Form completed by:

|  |  |  |
| --- | --- | --- |
| Name: |  | |
| Job Title/Role: |  | |
|  | |  |
| Signature: |  | |
| Date Completed: |  | |

PLEASE SCAN THIS FORM AND SEND BY EMAIL TO cope.trials@nds.ox.ac.uk