Serious Adverse Event (SAE) report for ARTIC PC antibiotics in LRTI study

(In case of a SAE, please complete this form on the ARTIC PC platform on www.Researchonline.org within 24 hours)

Patient study number
(*handwritten*)

A. Date of birth: ☐☐ ☐☐ ☐☐☐☐

Day Month Year

B. Description of SAE: ……..

C. Description of treatment: ……..

D1. Relevant tests/history: ☐ Yes ☐ No **D2. If yes, please describe**

……..

E1. Action on study medication (e.g. stopped, dosage reduced): ☐ Yes ☐ No ☐ Not applicable …….....

E2. If yes, please describe

F1. Date onset SAE: ☐☐ ☐☐ ☐☐☐☐

Day Month Year

F2. Stop date SAE: ☐☐ ☐☐ ☐☐☐☐

Day Month Year

G. SAE classification (see protocol):

- ☐ Death
- ☐ Life-threatening
- ☐ In-patient hospitalisation
- ☐ Disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☐ Other medical events requiring intervention to prevent one of the outcomes listed above

H. Relationship to study drug:

- ☐ None
- ☐ Unlikely
- ☐ Possible
- ☐ Probable
- ☐ Definite

I. Expectedness

- ☐ Expected
- ☐ Unexpected

J 1. Concomitant medication used: ☐ Yes ☐ No **J 2. If yes, please describe:**

……..

K. Subject outcome:

- ☐ Recovered
- ☐ Recovered with sequelae
- ☐ Still present
- ☐ Data not available
- ☐ Died