CTR CTIMP SERIOUS ADVERSE EVENT REPORTING FORM

Centre for Trials Research
Canolfan Ymchwil Treialon

EudraCT: 2018-001109-99 Sponsor Number: SPON1595-19

Participant Study Number | Participant DOB (D D M M Y Y Y Y) | Participant Initials

AZTEC
Azithromycin Therapy for Chronic Lung Disease

Trial site name ……..

Country of origin of SAE: UK

Report date: D D M M Y Y Y Y

Type of report: ☐ 1=Initial 2= Follow-up, number..... 3=Final

FOR INITIAL REPORT ONLY

Date site aware of SAE: D D M M Y Y Y Y

If reported to the CTR after 24 hours of becoming aware of SAE provide reason:

……..

Gender: ☐ 1=Male 2=Female

SAE DETAILS

Was the event serious?

☐ 1 = Yes 2 = No

(If Yes, please complete and return SAE form immediately
If No, record event on CRF)

Why was the event serious?

☐ 1 = Resulted in death
2 = Life-threatening
3 = Required inpatient hospitalisation or prolongation of existing hospitalisation
4 = Persistent or significant disability / incapacity
5 = Congenital anomaly / birth defect
6 = Other medically important condition

If participant has died: Date of death: D D M M Y Y Y Y Cause of death: _____

Event Description (Enter the MAIN EVENT in the first row followed by any associated symptoms. There should be only one MAIN EVENT per form. If there are two events, please complete two forms.) **Main diagnosis/symptom:**	**Severity Grade** 1= Mild 2=Moderate 3=Severe	**Date of onset** (dd/mm/yyyy)	**Date resolved** (dd/mm/yyyy)	**SAE Status** 1 = Resolved * 2 = Resolved with sequelae * 3 = Persisting 4 = Worsened 5 = Fatal (please complete death form) 6 = Lost to follow up	* **Specify sequelae** where applicable
Associated symptoms:					

CASE NARRATIVE

Give a concise medical description of the event including all relevant symptoms, body systems, and any additional information deemed relevant to the case. **Continued on separate sheet? (please tick)** ☐

Any tests/laboratory data applicable to this SAE? ☐ 1=Yes 2=No **Continued on separate sheet? (please tick)** ☐

Test name:					
Date:					
Normal range:					
Result: (inc. units)					

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INVESTIGATIONAL MEDICINAL PRODUCTS

IMP Name:	Date of first administration (dd/mm/yyyy)	Date of most recent administration (prior to this SAE) (dd/mm/yyyy)	Actual dose given at most recent administration (prior to this SAE) (include units)	Action taken due to SAE 1 = Drug withdrawn (temporary) 2 = Drug stopped 3 = Dose reduced 4 = Dose increased 5 = Dose delayed 6 = Dose reduced and delayed 7 = Dose not changed 8 = Unknown	Date action taken due to SAE (dd/mm/yyyy)
Azithromycin/placebo					

CONCOMITANT MEDICATIONS

Include any relevant therapies administered 30 days prior to the onset of the SAE; include concomitant medications, herbal medicines, and over the counter medicines. **Continued on a separate sheet? (please tick)**

Generic Drug Name	Date of first administration (dd/mm/yyyy)	Date of most recent administration (prior to this SAE) (dd/mm/yyyy)	Actual dose given at most recent administration (prior to this SAE) (include units)	Total Daily Dose prior to this SAE (include units)	Route 1= Oral 2=Intravenous 3=Subcutaneous 4=Other	Frequency

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CAUSALITY ASSESSMENT

To be completed by the Principal Investigator (or medically qualified delegate on trial delegation log)*; Do not delay submission if causality assessment is missing; causality assessment must then be gained as soon as possible however.
Please answer every question with a yes or no answer, i.e. insert number "1" or "2" in the boxes below.

1. Do you consider there is a reasonable possibility the SAE may have been caused by the IMP/ placebo? **a.** Azithromycin/placebo	1=Yes (definitely, probably, possibly related) 2=No (unlikely, not related)	a
2. Or is it related to a concomitant medication? If yes, please list trial drug (other than the IMPs)/concomitant medication/other treatment:	1=Yes 2=No	
3. Or is it caused by underlying disease?	1=Yes 2=No	
4. Or any other cause? Please specify:	1=Yes 2=No	
5. Or is it caused by an interaction between the IMP and any other concomitant medication?	1=Yes 2=No	

Investigator signature:

***Investigator name:** **Date:** (D D M M Y Y Y Y)

The SAE form must be completed by personnel authorised to complete CRFs and report SAEs on staff delegation log:

Completed by signature:

Completed by name: **Date:** (D D M M Y Y Y Y)