



00317454

SAE No.

SAE Visit Date 20 15 02 04

Initial Notification Date 20 15 05 28

Notification time 09 10

**1. Patient details**

TasP ID

1 3 6 3 9

Name

G.V.H

Sex

Male

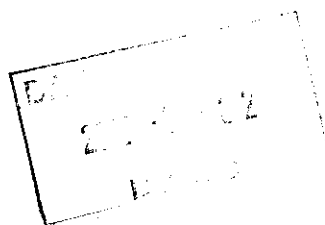
• Female

Date of birth

1 9 6 3 03 09

Enrolment date

20 1 2 04 05


**2. Measurements**

Height

Cms

Last known: Weight

47.5

Kgs

Weight Date

20 15 05 26

CD4 count

155

CD4 Date

20 15 02 04

Viral Load

2 1 0 9 7 7

Viral Load Date

20 15 02 11

**3. By which criteria is this adverse event considered to be "Serious"?**

Tick all that apply

- ☐ Resulted in death → Date of death Probable cause
- ☐ Life threatening (i.e. at risk of death at time of event)
- ☒ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital abnormality / birth defect
- ☐ Grade 4 clinical and biological events
- ☐ Other serious, medically-important condition → Specify

**4. Details of SAE**

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name
Date investigator became aware
Date of onset of SAE

1. Pulmonary TB 20 15 05 28 20 15 02 04

2. PCP 20 15 05 28 20 15 02 04

3.

4.

5.

**5. Description of SAE**

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

At TasP baseline visit (4/2/15) patient reported weight loss and cough. Amoxycillin did not help. On 8/2/15 patient was admitted to Alabisa hospital, and diagnosed with pulmonary TB and Pneumocystis jirovecii (PCP). Treatment commenced for both conditions. Patient was discharged from hospital on 14/2/15. She attended TasP clinic again on 26/5/15; Investigator was unaware of the admission.

## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Cotrimoxazole	tt	P.O.	Prophylaxis	20150204		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. Amoxycillin	1.5g	P.O.	Cough	20150204	20150209	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. Paracetamol	1g	P.O.	Cough/pain	20150204	20150214	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop

## 7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research?

Yes ☐ No ☒

7b. According to the physician, is this SAE related to any causes other than the research?

This includes the patient's medical history

Yes ☐ No ☒

Describe

Patient was immunocompromised + sick at entry into the trial.

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery 20150526

☒ Recovered without sequelae

or

Recovered with sequelae

Describe

## Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 20150528