



00125380

SAE No.

SAE Visit Date

2014 09 19

Initial Notification Date

2014 10 06

Notification time

16 10

1. Patient details

TasP ID

23633

Name

H.N.M.

Sex

Male

• Female

Date of birth

1972 09 08

Enrolment date

2013 04 26

2. Measurements

Height

159 Cms

Last known: Weight

68.4

Kgs

Weight Date

2014 09 13

CD4 count

651

CD4 Date

2014 09 13

Viral Load

1.0

Viral Load Date

2013 04 24

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. Anaemia 2014 09 16 2014 09 19

2. Parvovirus B19 2014 10 06 2014 09 19

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.

Anaemia (Hb = 4.3) was detected on TasP baseline bloods. Patient attended TasP clinic 19/9/14 and reported tiredness. She was pale, but stable, HR 80. She was unsure whether she could attend hospital, but did on 22/9/14 and was admitted until 25/9/14. She was transfused 2 units of blood. Investigations showed positive IgG and IgM for Parvovirus B19, which is the likely cause of her anaemia.

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. TDF/FTC/EFV	1 tablet	P.O.	HIV	20140508		<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. Amoxicillin	1.5g	P.O.	Chest Infection	20141013		<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.						<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
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

This patient is immunocompromised and at risk of opportunistic infection.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved



A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20140925

☒ Recovered without sequelae
or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name MELANIE HILL

Signature

Date form completed 20141006