



00317488

SAE No.

SAE Visit Date

Initial Notification Date 20 15 12 10

Notification time 09 30

1. Patient details

TasP ID

14 214

Name

V.M

Sex



Male

Female

Date of birth

1982 01 11

Enrolment date

20 13 05 09

2. Measurements

Height

159 Cms

Last known: Weight

57.9

Kgs

Weight Date

20 15 09 10

CD4 count

328

CD4 Date

20 15 08 03

Viral Load

< 40

Viral Load Date

20 15 05 20

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



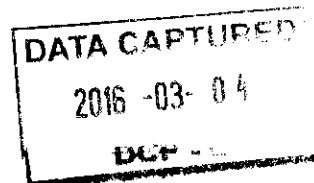
Congenital abnormality / birth defect



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. Grade 4 GGT 20 15 12 08 20 15 12 01

2.

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.

Bloods taken in TasP on 1/12/15 show ALT 89, ALP 193, GGT 1056.
The ↑ GGT is a grade 4 event.
Attempts have been made to contact the patient. They are currently unreachable. The case will be referred to the triaging team.
Cause of deranged LFT unknown.

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. Atripla	T	PO	HIV	2013 05 28		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								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

Has been in TAsP on atipla since 2013 without prior adverse events. Deranged LFT likely due to an external cause.

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

A complementary SAE notification must be submitted within 8 days

Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE

Name **MEANIE HILL**

Signature

Date form completed **2015 12 10**