

Serious Adverse Event Reporting
ANRS 12249 Initial SAE Notification

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002



00317480

SAE No.

SAE Visit Date

20151111

Initial Notification Date

20151117

Notification time

0930

1. Patient details

TasP ID

40143

Name

S.M.

Sex

~~Female~~
☒ Male

☐ Female

Date of birth

19640218

Enrolment date

20141021

2. Measurements

Height

151 Cms

Last known: Weight

74.0

Kgs

Weight Date

20151111

CD4 count

1123

CD4 Date

20151111

Viral Load

<40

Viral Load Date

20150528

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 20151113 20151111

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.

Patient did not attend TasP clinic for 3 months. Re-joined TasP on 11/11/15
Bloods taken on that date showed GGT 730 U/L ($> \times 10$ ULN). ALP=139
ALT 37 + Bilirubin 9. Patient was clinically well at the visit on 11/11/15.
Has been reviewed by TasP doctor before for deranged LFT's. Noted to abuse
alcohol. Patient will be monitored in TasP clinic.

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	T	PO	HIV	20141112		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. Thiamine	100mg	PO	Alcohol abuse	20141113		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> 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
Describe

No
Patient is known to drink alcohol to excess. This is unrelated to the trial.

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

Patient likely to have persistently deranged LFT's.

Physician reporting SAE

Name MELANIE HILL

Signature

Date form completed 20151117