

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



00317492

SAE No.

SAE Visit Date

Initial Notification Date 20 16 02 29

Notification time 15 59

1. Patient details

TasP ID

13639

Name

G.V.H.

Sex

Male

Female

Date of birth

1963 01 01

Enrolment date

2015 02 04

2. Measurements

Height

Cms

Last known: Weight

44.5

Kgs

Weight Date

2016 02 01

CD4 count

427

CD4 Date

2015 10 27

Viral Load

290

Viral Load Date

2015 10 27

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

Tick all that apply

- ☒ Resulted in death → Date of death 2016 02 20 Probable cause UNKNOWN
- ☐ 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. Death 2016 02 29 2016 02 20

2.

3.

4.

5.

5. Description of SAE

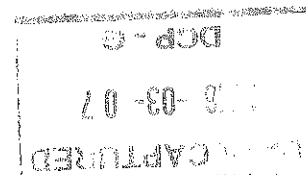
Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

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

Message from patient's family: Patient died suddenly after complaining of shortness of breath and headache. No medical help was sought.

last seen in TasP clinic to collect treatment on 14/16, when she complained of painful feet + painful tongue. Previously hospitalised Feb 2015 with PCP + PTB.

Seen by M.O. on 27/10/15 due to deranged LFT's. She was known to abuse alcohol.



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	2015 05 26		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						<input type="radio"/> Poss. related	<input checked="" type="radio"/> No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
2.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
3.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
4.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
5.						<input type="radio"/> Unrelated		None
						<input type="radio"/> Poss. related	Yes	Reduce
						<input type="radio"/> Cannot be assessed	No	Interrupt
								Stop
6.						<input type="radio"/> Unrelated		None
						<input type="radio"/> Poss. related	Yes	Reduce
						<input type="radio"/> 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

Patient was immunocompromised and known to abuse alcohol.

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 MELAME HILL

Signature

Date form completed 2016 02 29