

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



00317494

SAE No.

SAE Visit Date

2016 03 22

Initial Notification Date

2016 03 24

Notification time

14 00

1. Patient details

TasP ID

47686

Name

S.N.

Sex

Male

☒ Female

Date of birth

1960 07 06

Enrolment date

2. Measurements

Height

152 cms

Last known: Weight

69.1

Kgs

Weight Date

2016 02 01

CD4 Date

2016 11 05

Viral Load Date

2016 11 08

CD4 count

<40

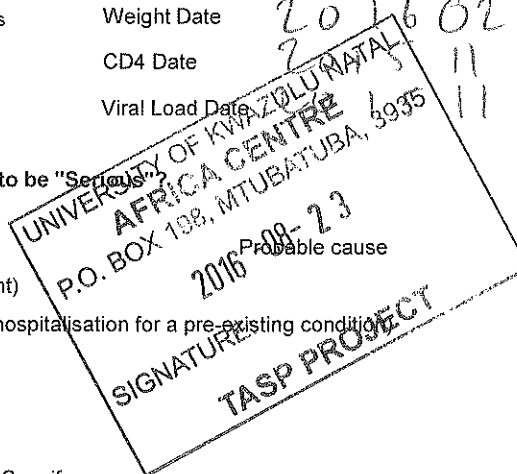
Viral Load

461

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

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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 ALT + GGT 2016 03 24 00 00 00 00 00

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 22/3/16 show ALT 580; ALP 442; GGT 517.
LFT's in Nov 2015 were mildly deranged with ALT 61; ALP 261; GGT 365.
TFT, Ca²⁺, Mg, Phosphate + Hep C were negative in November 2015.
This patient will be traced for urgent review by a doctor.

6. Medications

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

| | Generic Name | Daily dose | Route of administration | Indication | Date started | Causality assessment | Expected reaction? (BNF/SPC) | Action taken |
|----|--------------|------------|-------------------------|------------|--------------|--|--------------------------------------|---------------------------------------|
| | | | | | Date stopped | | | |
| 1. | Atripla | i | PO | HIV | 2014 11 25 | 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. | | | | | | 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

Patient is HIV positive, on ART prior to Tasp. Cause of LFT derangement unclear at present.

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

MELANIE HILL

Signature

[Signature]

Date form completed

20160324