



00317455

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

SAE No.

SAE Visit Date

Initial Notification Date 20 15 06 24 Notification time

1. Patient details

TasP ID

14325

Name

S.Z.

Sex



Male

Female

Date of birth

19890923

Enrolment date

20120724

2. Measurements

Height

177 Cms

Last known: Weight

53.3

Kgs

Weight Date

20150527

CD4 count

437

CD4 Date

20150527

Viral Load

12350

Viral Load Date

20150216

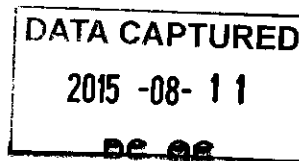
3. By which criteria is this adverse event considered to be "Serious"?

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. Psychiatric Problem 20 15 06 22 20 15 06 06

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.

TasP was informed that this patient experienced a psychiatric problem and was admitted to Hlabisa hospital on 6/6/15 to 16/6/15.

On 22/6/15 a TasP doctor attended Hlabisa to review the inpatient notes. The inpatient notes have been misplaced. Diagnosis + treatment remain unknown. The patient will be reviewed in TasP clinic for further information.

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. | TDF/FTC/EFV | T | PO | HIV | 20150224 | Unrelated | <input checked="" type="radio"/> Yes | 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 ☒ → Further information to follow in Complimentary SAE.
- 7b. According to the physician, is this SAE related to any causes other than the research? ☒ Yes ☐ No
This includes the patient's medical history
Describe: Anybody is at risk of psychiatric illness. More information will follow once patient is reviewed + diagnosis elicited.

8. SAE Outcome

- Died
Unknown to date
Ongoing
Improved
Recovered → A complementary SAE notification must be submitted within 8 days
- Recovered → Date of recovery 20150616
Recovered without sequelae
or
Recovered with sequelae
Describe

Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 20150624