



00648502

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

SAE No.

SAE Visit Date

20160408

Initial Notification Date

20160411

Notification time

1100

1. Patient details

TasP ID

54994

Name

N.N.

Sex

Male

☒ Female

Date of birth

19840526

Enrolment date

20160201

2. Measurements

Height

Cms

Last known: Weight

36.5

Kgs

Weight Date

20160301

CD4 count

457

CD4 Date

20160201

Viral Load

<40

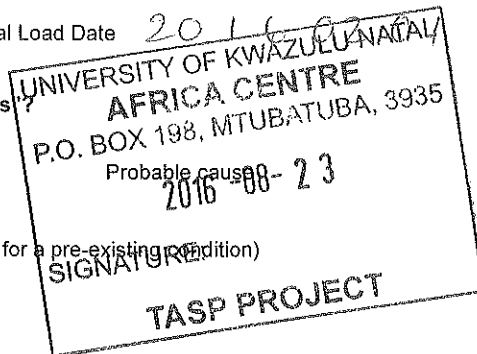
Viral Load Date

20160301

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. Dyspnoea 20160408 20160321

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.

Participant newly enrolled in trial. Already on ART (TDF/FTC/EFV) with CD4 457 & viral load undetectable. She has history of multiple episodes of pulmonary TB resulting in lung fibrosis. Relatives report that she has been admitted to hospital with severe shortness of breath since 2016/03/21. More information to follow when it is available.

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. Tenofovir | 300mg | oral | HIV | 20140507 | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 2. Emtricitabine | 200mg | oral | HIV | 20140507 | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 3. Efavirenz | 600mg | oral | HIV | 20140507 | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 4. Budesonide | 2 puffs | inhaler | COAD | 20160204 | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 5. Asthavent | 2 puffs PRN | inhaler | COAD | 20160204 | | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 6. | | | | | | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input checked="" type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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

At with multiple episodes pulmonary
7b. Susceptible to dyspnoea due
to lung fibrosis

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery

or ☐ Recovered without sequelae

☐ Recovered with sequelae

→ Describe

Physician reporting SAE

Name

GUG'EHLE MIKHULISI

Signature

Date form completed

20160411