

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



00648507

SAE No.

SAE Visit Date

2016

Initial Notification Date

2016 06 14

Notification time

10 00

1. Patient details

TasP ID

20115

Name

S.F.G.

Sex



Male

Female

Date of birth

1967 01 10

Enrolment date

2013 03 20

2. Measurements

Height

180 Cms

Last known: Weight

52.6

Kgs

Weight Date

2016 04 21

CD4 count

425

CD4 Date

2016 04 21

Viral Load

<40

Viral Load Date

2016 04 21

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

Tick all that apply

☒ Resulted in death → Date of death 2016 05 28 Probable cause unknown

☐ Life threatening (i.e. at risk of death at time of event)

☐ Caused or prolonged hospitalisation (not elective hospitalisation for 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

Date of onset of SAE

became aware

1. Death; cause unknown 2016 06 13 2016 05 28

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 on Atripla, with CD4 count 435 & viral load <40. He missed May appointment; Trackers were sent to household. Upon enquiry, relatives reported that he had been admitted to hospital with severe shortness of breath & died in hospital on 28/05/2016. No hospital records found to confirm this. More details to follow if they become 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 | 2013 08 27 | | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" 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 | 2013 08 27 | | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" 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 | 2013 08 27 | | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" 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. | | | | | | <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 |
| 5. | | | | | | <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 |
| 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?

☒ Yes ☐ No

This includes the patient's medical history

Describe

From relatives: patient seemed to have been unwell; resulting in admission & death.

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 GUGLIE MOHULI

Signature

Date form completed 20160614