

Serious Adverse Event Reporting
ANRS 12249 Initial SAE Notification


00423097

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

SAE No.

SAE Visit Date

20150421

Initial Notification Date

20150423

Notification time

1. Patient details

TasP ID

42844

Name

M.K.

Sex

☒ Male

☐ Female

Date of birth

19520324

Enrolment date

20141021

2. Measurements

Height

153 Cms

Last known: Weight

63.3

Kgs

Weight Date

20150413

CD4 count

463

CD4 Date

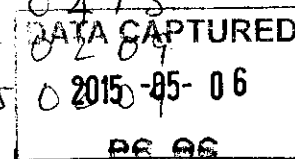
20150204

Viral Load

1738

Viral Load Date

20150204


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

Tick all that apply

- ☒ Resulted in death → Date of death 20150413 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 20150421 201504

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.

Daughter informed clinic staff that patient was complaining of shortness of breath. No other complaints raised. Died at home shortly after.

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. ^{Xmp} LAMIVUDINE AZT/3TC D4T | T b.i.d | PO | HIV | 20070622 | 20141125 | <input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input checked="" 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. ISONIAZID | 300mg | PO | TB PROPHYLAXIS | 20150413 | | <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. PYRIDOXINE | 25mg | PO | TB PROPHYLAXIS | 20150413 | | <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. EFAVIRENZ | 600mg | PO | HIV | 20070622 | | <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 |
| 5. HYDROCHLOROTHIAZIDE | 12.5mg | PO | HYPERTENSION | 20140901 | | <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 |
| 6. AZT/3TC | T b.i.d | PO | HIV | 20141125 | | <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 |

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

NOT ENOUGH INFORMATION

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

COLLINS INCHI

Signature

Xmp

Date form completed

20150423