

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



00658346

SAE No.

SAE Visit Date

Initial Notification Date 20 16 04 22

Notification time 16 00

1. Patient details

TasP ID

S 0 0 2 1

Name

K.M.

Sex

☐ Male

☒ Female

Date of birth

19 59 11 11

Enrolment date

20 15 03 02

DATA CAPTURE
2016 -07- 22
DOD - X

2. Measurements

Height

1 6 2 Cms

Last known: Weight

56 . 2

Kgs

Weight Date

20 16 04 04

CD4 count

49

CD4 Date

20 15 09 17

Viral Load

1 9 5 2 9 2

Viral Load Date

20 16 03 03

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. Diarrhoea 20 16 04 22 20 16 04 20

2. Chest Infection 20 16 04 22 20 16 04 20

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 nursing staff report patient was admitted to Hlabisa Hospital on 20/4/16 with diarrhoea and a lower respiratory chest infection.

She was seen in TasP Clinic on 4/4/16 with the same complaints.

BP was 89/54 on that date. An ambulance was called but it did not arrive.

She was switched to 2nd line ART (lamzid/aluvia) on 4/4/16.

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. Lamiid	2 tabs	PO	HIV	2016 04 04		<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. Aluvia	4 tabs	PO	HIV	2016 04 04		<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input 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 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 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 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

Patient was severely immunocompromised. Aluvia can cause diarrhoea, but patient was complaining of diarrhoea before starting to Aluvia.

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 2016 04 22