

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

00125373

SAE No.

SAE Visit Date

Initial Notification Date

20140901

Notification time

16 45

1. Patient details

TasP ID

24188

Name

T.T.

Sex

Male

Female

Date of birth

19580831

Enrolment date

20130410

2. Measurements

Height

Cms

Last known: Weight

69.6

Kgs

Weight Date

20140715

CD4 count

1654

CD4 Date

20140204

Viral Load

<50

Viral Load Date

20140212

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

Tick all that apply



Resulted in death → Date of death

20140819

Probable cause

Unknown abdominal pathology



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. Dysuria 20140901 20140816

2. Abdominal Pain 20140901 20140816

3. Tachypnoea 20140901 20140816

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.

The family of this patient informed us (TasP) of their death. On 16/8/14 she became unwell with abdominal pain. They sought medical help at Hlabisa hospital on 19/8/14. I have reviewed the hospital notes. She died on the same day as admission. She had dysuria + abdominal pain, admitted with a diagnosis of "complicated cystitis". She was tachypnoeic during the hospital stay; however her blood results were normal. Abdominal USS normal. She died suddenly.

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. Atripla	One tablet	Po	HIV	20130510		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. HCTZ	12.5mg	PO	Hypertension			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	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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 ☒

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

The patient died of a presumed urinary tract infection causing sepsis, although she was not referred for post-mortem.

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

Date form completed 20140901