

**Serious Adverse Event Reporting**


00199216

**ANRS 12249 Complementary SAE Notification**

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

Initial Notification Date

2014 08 28

i.e. Date of original Initial Notification Form

Complementary Notification Date

2014 09 19

**1. Patient details**

TasP ID

33311

Name

X.M.

Sex

☒ Male

☐ Female

Date of birth

1994 03 04

Enrolment date

2014 07 29

**2. Description of the reported SAE**

This patient was admitted on 23/8/14 to Hlabisa hospital with diarrhoea. He was discharged but referred back on 14/9/14 with weakness, ascites, cough and oedema. Is on antiretroviral therapy, suppressed viral load but CD4 45.

Date of SAE onset

2014 08 12

**3. Complementary information**

TasP telephoned the patient on 19/9/14 to see if he was still admitted. We were informed by his family that he died in hospital on 15/9/14. The presumed cause of death is tuberculosis. His hospital notes are yet to be reviewed. Further information will be supplied after his notes are seen.

**4. New diagnosis?**

Yes → Describe

☒ No

Date of new diagnosis

**5. Patient treatment**

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7

## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
1.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related Cannot be assessed

## 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 was severely immunocompromised and malnourished.

## 8. SAE Outcome

☒ Death

→ Date of death

2014 09 15

Probable

Diagnosis Tuberculosis

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

## Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature



Date form completed 2014 09 19