



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
Ukuphila kwami, ukuphila kwethu (my health for our health)

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00317363

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

20160301

i.e. Date of original Initial Notification Form

Complementary Notification Date

20160422

1. Patient details

TasP ID

46237

Name

Z.G.

Sex

Male

☒ Female

Date of birth

19621030

Enrolment date

20131013

2. Description of the reported SAE

Known to have Multiple Myeloma.  
with epistaxis.

Admitted to Hlabisa Hospital on 27/2/2016

Date of SAE onset

20160227

3. Complementary information

Hospital discharge letter now available. Was admitted to the hospital on 28/2/16 and discharged on 17/3/16. Did not have epistaxis - was admitted with a cough & fever. Treated for lower respiratory tract infection. Re-referred to Hlabisa Hospital for management of multiple myeloma. Decision made to transfer to Hlabisa Hospital.

4. New diagnosis?

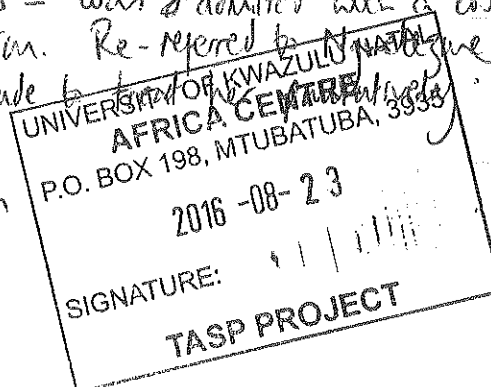
☒ Yes ☐ Describe

No

Lower Respiratory Tract Infection

Date of new diagnosis

20160228



5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

No

N/A

Which treatment?

Antibiotics (not specified)

Date discontinued

UUUUUUUUUU

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

Generic Name	Dose	Frequency	New judgement of causality
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

This patient has multiple myeloma + was bedbound. At high risk of respiratory tract infections.

## 8. SAE Outcome

Death → Date of death

Probable Diagnosis \_\_\_\_\_

Unknown to date

Ongoing

Improved

Worsened

→ Another complementary SAE notification form must be submitted.

☒ Recovered

→ Date of recovery 20160317

☒ Recovered without sequelae (of lower respiratory tract infection)

or

Recovered with sequelae

Describe

## Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature 

Date form completed 20160422