



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
Ukaphila kwami, ukaphila kwethu / my health, for our health

Ukaphila kwami, ukaphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00199205

## 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

20140704

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140728

### 1. Patient details

TasP ID

26592

Name

L.N.

Sex

☒ Male

☐ Female

Date of birth

19960618

Enrolment date

20131112

### 2. Description of the reported SAE

HIV Positive since 2007. Previous TB lymphadenitis & TB arthritis.  
Last treated for TB in 2013. Presents with pain & hotness of left leg.  
Swollen & painful left elbow with decreased range of movement.

Date of SAE onset 20140627

### 3. Complementary information

Admitted to Hlabisa Hospital 02/7/2014. Started on Intravenous Augmentin  
and Gentamycin. TB screening (CXR, Genexpert) done; results  
negative. Responded well to treatment. Diagnosed as HIV associated  
arthropathy and discharged on 9/7/2014.

### 4. New diagnosis?

☒ Yes → Describe

HIV Associated Arthropathy

No

Date of new diagnosis 20140709

### 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  
Describe

No

Patient with advanced disease and severe immunosuppression.

## 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 20140709

☒ Recovered without sequelae  
or

Recovered with sequelae

→ Describe

## Physician reporting SAE Complementary Notification

Name DR G MCHULIST

Signature

Date form completed 20140728