

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
TasP (Ukaphila kwami) is a vaccine for our health**Ukaphila kwami, ukuphila kwethu****Africa Centre TasP Trial****SAE-AC****Serious Adverse Event Reporting**

00317356

ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

20150923

i.e. Date of original Initial Notification Form

Complementary Notification Date

20151023

1. Patient details

TasP ID

34422

Name

S.B.M.

Sex



Male

Female

Date of birth

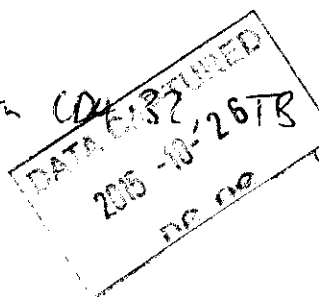
19820328

Enrolment date

20131203

2. Description of the reported SAE

Patient defaulted ART. Returned to clinic with CD4 132 and a UTI. Subsequently died.



Date of SAE onset 20150823

3. Complementary information

Now confirmed date of death was 24 September 2015.
The patient died in Hlabisa hospital.

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

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

Patient was lost to follow-up + severely immunosuppressed.

8. SAE Outcome

Death

→ Date of death

20150924

Probable Diagnosis

Stage IV HIV

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

Opportunistic infections
Cryptococcal antigenaemia
?TB
UTI.

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature

[Signature]

Date form completed 20151023