



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukuphila kwami, ukuphila kwethu)

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Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00317360

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

20151120

i.e. Date of original Initial Notification Form

Complementary Notification Date

20151204

1. Patient details

TasP ID

46656

Name

P.M.

Sex



Male

Female

Date of birth

19831120

Enrolment date

20141008

2. Description of the reported SAE

Referred to Hlabisa hospital with abscess of lower lip

Date of SAE onset

20151112

3. Complementary information

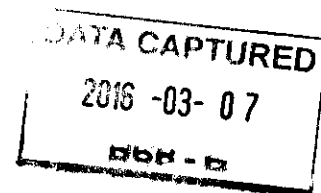
Admitted in Hlabisa 23/11/15 to 27/11/15. Did not have I+D. Treated with IV antibiotics + mouthwash.
Necrotic area has left a 1cm wide hole in his lip making eating + drinking difficult.

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

Immunocompromised, so at risk of abscess.

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 2015 11 27

☒ Recovered without sequelae
or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature 

Date form completed 2015 12 04