



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



00057261

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

i.e. Date of original Initial Notification Form

Complementary Notification Date

1. Patient details

TasP ID

12027

Name

SIPHO M. STHOLE

Sex

☒ Male

☐ Female

Date of birth

19640929

Enrolment date

2. Description of the reported SAE

Coughing up blood 12 weeks
Chest pains
hr lung crackles

Date of SAE onset

3. Complementary information

4. New diagnosis?

☒ Yes → Describe
☐ No

Haemoptysis

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. <i>ATRIMA</i>	<i>tab</i>	<i>route</i>	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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? ☐ Yes ☐ No
This includes the patient's medical history
☐ Describe

8. SAE Outcome

Unknown to date
 Ongoing
 Improved
 Worsened
 Recovered

☐ Another complementary SAE notification form must be submitted within 8 days from now.
☐ Date of recovery *2014-01-14*
☐ Recovered without sequelae
 or
☐ Recovered with sequelae
☐ Describe

Physician reporting SAE Complementary Notification

Name

Signature

Date form completed