



Antiretroviral Treatment as Prevention - ANRS 12249
Ukaphila kwami, ukuphila kwethu

Makhwela

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Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00059972

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

20131121

i.e. Date of original Initial Notification Form

Complementary Notification Date

20131129

1. Patient details

TasP ID

23474

Name

B.N.

Sex

☒ Male

☐ Female

Date of birth

19610204

Enrolment date

20130429

2. Description of the reported SAE

Participant died in hospital on 10/11/2013 according to relative but records could not be retrieved from hospital

Date of SAE onset

20131110

3. Complementary information

Participant did not go to hospital but went to see a traditional healer. Was complaining of shortness of breath of 3 days duration. traditional healer kept him overnight at his place and discharged home afterwards. Patient died at home on 10/11/2013

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

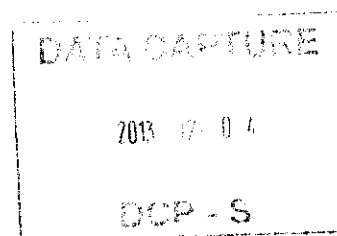
Which treatment?

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. ATRIDLA T0F/FTC/EFV	T 0.5	0.5	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" 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

Shortness of breath, probably had some respiratory problem.

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
 Recovered without sequelae
 or
 Recovered with sequelae
 → Describe

Physician reporting SAE Complementary Notification

Name: COLLINS / WUJ
 Signature: [Signature]
 Date form completed: 2013 11 29