

Serious Adverse Event Reporting
Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for our health)


00317347

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

20150904

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150921

1. Patient details

TasP ID

47134

Name

S.K.D.

Sex



Male

Female

Date of birth

19730711

Enrolment date

20141010

2. Description of the reported SAE

Participant in intervention arm, not yet on ART, CD4 313, viral load 499365.
Had low Hb & platelets at baseline. Developed haemoptysis and was referred to hospital.
Chest X-ray confirmed pulmonary TB. He was admitted to start treatment.

Date of SAE onset 20150902

3. Complementary information

Participant responded well to TB treatment. Was discharged on 15/09/2015.
He was referred to local clinic for monitoring & collection of treatment.
He will be followed up at local clinic for initiation & monitoring of ART.

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

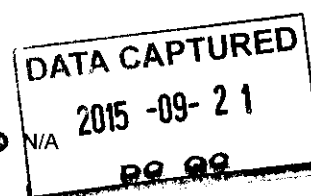
☒ N/A

→ 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 ☒

Describe

No ☐

Participant had TB symptoms at baseline.

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

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Participant on TB treatment.

Physician reporting SAE Complementary Notification

Name GUG'ELINE MKHULISI

Signature

Date form completed 20150921