



TasP

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

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Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00317311

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

20160411

i.e. Date of original Initial Notification Form

Complementary Notification Date

20160520

1. Patient details

TasP ID

54994

Name

N-N.

Sex

Male



Female

Date of birth

19840526

Enrolment date

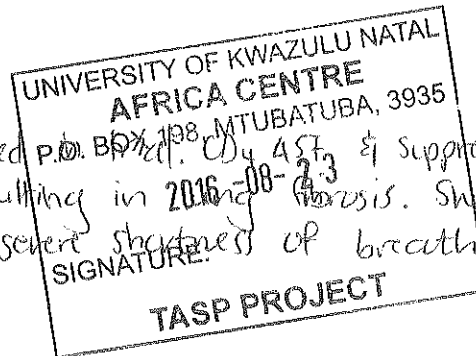
20160201

2. Description of the reported SAE

Participant on ART, newly enrolled P.O. Box 138, MTUBATUBA, 3935. CD4 453 & suppressed viral load. Multiple previous episodes of PTB, resulting in 2016-08-23 & severe shortness of breath. She was admitted to hospital on 21/3/2016 with severe shortness of breath.

Date of SAE onset

20160321



3. Complementary information

Hospital notes reviewed: She was oxygen dependent on admission & was on continuous oxygen. She was treated with IV antibiotics & inhaled broncho-dilators. She was also treated by dietician & physiotherapist for weight loss & mobilisation respectively. She was discharged on 11/04/2016.

4. New diagnosis?

☒ Yes → Describe

Post TB Bronchiectasis

No

Date of new diagnosis

20160401

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

Due to multiple episodes PTB; Post TB bronchiectasis can be an expected complication.

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 20160411

☒ Recovered without sequelae
or

Recovered with sequelae

Describe

Physician reporting SAE Complementary Notification

Name GUGLIELMO MACHULSI

Signature

Date form completed 20160520