



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Uphila is now, uphila is better (my health for my health))

Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

Mchakwini

SAE-AC

Serious Adverse Event Reporting



00059962

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

20130607

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130718

1. Patient details

TasP ID

25034

Name

Chonco Xolani Mlungisi

Sex

☒ Male

☐ Female

Date of birth

19830322

Enrolment date

20130603

DATA CAPTURED

2013-07-26

DCP G

2. Description of the reported SAE

The patient Chonco Xolani was admitted at Hlabisa hospital since 2013-06-06 and was said be on TB treatment and art but never improved died 2 weeks ago according to relatives
Date of SAE onset 20130606.

3. Complementary information

Patient was diagnosed with Pulmonary TB, and bacterial pneumonia whilst in hospital.

4. New diagnosis?

☒ Yes → Describe

Pulmonary TB.

☐ No

Date of new diagnosis

20130606.

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? ☒ Yes ☐ No
This includes the patient's medical history

Describe **Pulmonary TB**
Advanced HIV infection

8. SAE Outcome

Unknown to date
Ongoing
Improved
Worsened
Recovered

→ Another complementary SAE notification form must be submitted within 8 days from now.

Died on 26/06/2013.

→ Date of recovery

Recovered without sequelae
or
Recovered with sequelae
→ Describe

Physician reporting SAE Complementary Notification

Name **COLINS Iwuji**
Signature **Ximp**
Date form completed **2013 07 18**