



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Stop the event, stop the virus (my health for our health))

Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00093235

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

20130805

i.e. Date of original Initial Notification Form

Complementary Notification Date

20131107

1. Patient details

TasP ID

28995

Name

M.Z

Sex

☒ Male

☐ Female

Date of birth

19750228

Enrolment date

20130613

2. Description of the reported SAE

Multi-drug resistant TB

Date of SAE onset

20130917

3. Complementary information

Patient died at home on 1/11/2013. Mother said he was poorly adherent to his treatment

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

2013-11-21

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Dose	Frequency	New judgement of causality
1. TENOFOVIR	300mg	PO QD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. LAMIVUDINE	300mg	PO QD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. EFAVIRENZ	600mg	PO QD	<input checked="" 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 MDR - TB

8. SAE Outcome

Unknown to date
 Ongoing
 Improved
 Worsened
 Recovered → Date of recovery

Dead
 1/11/2013

☐ Recovered without sequelae
 or
☐ Recovered with sequelae
 → Describe

Physician reporting SAE Complementary Notification

Name

DR. CORINNA L. W. G. I.

Signature

[Signature]

Date form completed

20131107