



Antiretroviral Treatment as Prevention - ANRS 12249
Ukaphila kwami ukuphila kwethu (our health, for our health)



00442975

Ukaphila kwami, ukuphila kwethu
Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20150206

Initial Notification Date

20150609

Notification time

1. Patient details

TasP ID

49770

Name

T.M.

Sex

Male

☒ Female

Date of birth

19880228

Enrolment date

20150413

2. Measurements

Height

177 cms

Last known: Weight

60.4

Kgs

Weight Date

20150525

CD4 count

543

CD4 Date

20150413

Viral Load

<40

Viral Load Date

20150413

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☐ Resulted in death → Date of death Probable cause
- ☐ Life threatening (i.e. at risk of death at time of event)
- ☒ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital abnormality / birth defect
- ☐ Grade 4 clinical and biological events
- ☐ Other serious, medically-important condition → Specify

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name

Date investigator
became aware

Date of onset of SAE

1. PROBABLE TB 20150605 20150101

2.

3.

4.

5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

5 months history of cough productive of yellowish sputum, weight loss and night sweats. previous TB in 2010. XPERT MTB x2 negative. Culture is pending. Admitted to hospital on 2/6/2015 for further investigation.

6. Medications

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

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. ATRIPLA (ZST/FTC/EFV)	245/200/600mg	PO	HIV			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
2.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop

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

probable TB, present at baseline

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name

COLINS Iwan
Xp

Signature

Date form completed

20150609