



TasP

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

Mchatswini
Ukaphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AI

01/11/13

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

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

00057418

SAE No.

SAE Visit Date

20130607

Initial Notification Date

20130607

Notification time

1. Patient details

TasP ID

25034

Name

XC

Sex

☒ Male

☐ Female

Date of birth

19830322

Enrolment date

20130603

2. Measurements

Height

167 Cms

Last known: Weight

68.8

Kgs

Weight Date

20130603

CD4 count

51

CD4 Date

20130603

Viral Load

206600

Viral Load Date

20130603

Pending

123456
2013/06/12

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

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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

Probable cause

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. SUSPECTED
PULMONARY TB

20130607

20130606

DATA CAPTURE

2013-06-19

DCP - F

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.

On the visit of 3/6/2013, patient complained of cough, weight loss and diarrhoea which was on & off.
Sputum was collected for acid fast bacilli + culture.
He was admitted on 7/6/2013
Complementary information to follow

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. / | | | | | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 2. / | | | | Y Y Y Y M M D D Y Y Y Y M M D D | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 3. / | | | | | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 4. / | | | | Y Y Y Y M M D D Y Y Y Y M M D D | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 5. / | | | | Y Y Y Y M M D D Y Y Y Y M M D D | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop |
| 6. / | | | | Y Y Y Y M M D D Y Y Y Y M M D D | <input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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?
This includes the patient's medical history

☒ Yes ☐ No

Describe

Advanced HW

8. SAE Outcome

☐ Died

☐ Unknown to date

☒ Ongoing

☐ Improved

☐ Recovered

A complementary SAE notification must be submitted within 8 days

Date of recovery Y Y Y Y M M D D

☐ Recovered without sequelae

or ☐ Recovered with sequelae

Describe

Physician reporting SAE

Name

DR COLLINS IWHJ

Signature

Xmp

Date form completed

20130607