



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Detailed Events: complete Events only usable for our facility)



00057416

Shungu
Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI

21 Jan 2013

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

SAE No.

SAE Visit Date

2013 0511

Initial Notification Date

2013 0530

Notification time

1710

1. Patient details

TasP ID

15131

Name

N.N

Sex

☐

Male

☒

Female

Date of birth

19820213

Enrolment date

20130220

2. Measurements

Height

152 Cms

Last known: Weight

44.5

Kgs

Weight Date

20130502

CD4 count

30

CD4 Date

20130220

Viral Load

659400

Viral Load Date

20130402

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

Tick all that apply

☒

Resulted in death → Date of death 20130511 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

DATA CAPTURED
2013-05-10
DCP G

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.

DIARRHOEA

20130530

UNKNOWN

2.

Y Y Y Y M M D D Y Y Y Y M M D D

3.

Y Y Y Y M M D D Y Y Y Y M M D D

4.

Y Y Y Y M M D D Y Y Y Y M M D D

5.

Y Y Y Y M M D D Y Y Y Y M M D D

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.

Nurse phoned patient to attend for review and optimisation of ART but was informed by patient's sister that patient died on the way to clinic. Was complaining of diarrhoea. More information unlikely to be available. Patient has advanced HIV and has adhered poorly to ART. First started ART in 2007.

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. TENOFOVIR	300mg	PO	HW	20130305		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. LAMIVUDINE	300mg	PO	HW	20130305		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. EFAVIRENZ	600mg	PO	HW	20130305		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.						<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.						<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.						<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 in patient who interrupted treatment on multiple occasions

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

COLLINS (WUW)

Signature

Xup

Date form completed

20130530