



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Hepatitis B virus, hepatitis C virus (see label for our health))

EGEDENI
Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AI
v31 jan 2013

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



00057406

SAE No. _____

SAE Visit Date

2013 07 16

Initial Notification Date

2013 07 26

Notification time _____

1. Patient details

TasP ID

21 695

Name _____

Sex

☐ Male

☒ Female

Date of birth

19 57 04 03

Enrolment date

2013 03 19

DATA CAPTURED

2013-07-30

DCP - G

2. Measurements

Height

1.56 Cms

Last known: Weight

74 Kg

Kgs

Weight Date

2013 07 16

CD4 count

675

CD4 Date

2013 07 16

Viral Load

<50

Viral Load Date

2013 07 16

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

Date of onset of SAE

became aware

1. RAISED GAMMA

2013 07 25 2013 07 16

GLUTAMYL TRANS
FERASE

2. Y Y Y Y M M D D Y Y Y Y M M D D

3. _____

4. Y Y Y Y M M D D Y Y Y Y M M D D

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.

GGT started rising in March 2013 but levels were below the limits considered severe. Blood test taken on 16/7/2013 showed GGT now > 10 x U.L.N. The other liver enzymes are essentially normal.

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. STAVUDINE	60mg	PO	HW	20040520	20130418	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
2. LAMIVUDINE	300mg	PO	HW	20040520	20130418	Unrelated	<input checked="" type="radio"/> Yes	None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
3. EFVIRENZ	600mg	PO	HW	20040520	20130418	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. ATRIPLA	300/200/600	PO	HW	20130418		Unrelated	<input checked="" type="radio"/> Yes	None
TDF/FTC/EFV						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop

DATA CAPTURED
2013-07-30
PCR-C

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
Describe

No
GGT started rising whilst patient was on DT/3TC/EFV before joining the research.

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 Iwan

Signature

[Signature]

Date form completed

20130726