



Antiretroviral Treatment as Prevention - ANRS 12249
(Uphila: know, uphold, together, my health for our health)

Ukuphila 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



00093291

SAE No.

SAE Visit Date

20140430

Initial Notification Date

20140509

Notification time

1. Patient details

TasP ID

25615

Name

TG

Sex

☒ Male

☐ Female

Date of birth

19720902

Enrolment date

20130905

2. Measurements

Height

182 Cms

Last known: Weight

67.5

Kgs

Weight Date

20140508

CD4 count

338

CD4 Date

20140304

Viral Load

250

Viral Load Date

20131128

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

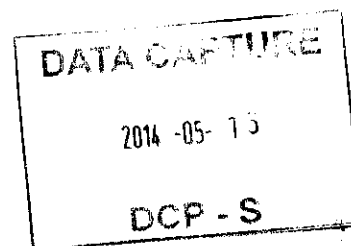
1. ACUTE RENAL FAILURE 20140508 20140429

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.

Presented to clinic on 30/4/2014 with diarrhoea and Vomiting. offered hospital admission for rehydration but refused. U/E done on the day showed Creatinine of 537. He was reviewed on 8/5/2014 and transferred to hospital by ambulance for further management.

6. Medications

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

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	TENOFOVIR	300mg	PO	HW	2013 08 19	<input type="radio"/> Unrelated	<input type="radio"/> Yes	<input type="radio"/> None
					2013 11 04	<input type="radio"/> Poss. related	<input type="radio"/> No	<input type="radio"/> Reduce
						<input type="radio"/> Cannot be assessed		<input type="radio"/> Interrupt
								<input type="radio"/> Stop
2.	LAMIVUDINE	300mg	PO	HW	2013 08 19	<input type="radio"/> Unrelated	<input type="radio"/> Yes	<input type="radio"/> None
					2013 11 04	<input type="radio"/> Poss. related	<input type="radio"/> No	<input type="radio"/> Reduce
						<input type="radio"/> Cannot be assessed		<input type="radio"/> Interrupt
								<input type="radio"/> Stop
3.	EFAVIRENZ	600mg	PO	HW	2013 08 19	<input type="radio"/> Unrelated	<input type="radio"/> Yes	<input type="radio"/> None
					2013 11 04	<input type="radio"/> Poss. related	<input type="radio"/> No	<input type="radio"/> Reduce
						<input type="radio"/> Cannot be assessed		<input type="radio"/> Interrupt
								<input type="radio"/> Stop
4.	TDF/FTC/EFV	300/200/600	PO	HW	2013 11 04	<input type="radio"/> Unrelated	<input checked="" type="radio"/> Yes	<input type="radio"/> None
						<input checked="" type="radio"/> Poss. related	<input type="radio"/> No	<input type="radio"/> Reduce
						<input type="radio"/> Cannot be assessed		<input type="radio"/> Interrupt
								<input checked="" type="radio"/> Stop
5.						<input type="radio"/> Unrelated	<input type="radio"/> Yes	<input type="radio"/> None
						<input type="radio"/> Poss. related	<input type="radio"/> No	<input type="radio"/> Reduce
						<input type="radio"/> Cannot be assessed		<input type="radio"/> Interrupt
								<input type="radio"/> Stop
6.						<input type="radio"/> Unrelated	<input type="radio"/> Yes	<input type="radio"/> None
						<input type="radio"/> Poss. related	<input type="radio"/> No	<input type="radio"/> Reduce
						<input type="radio"/> Cannot be assessed		<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

Severe gastroenteritis resulting in acute renal failure exacerbated by tenofovir prescribed before joining trial

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

2014 05 09