

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



00658348

SAE No.

SAE Visit Date

Initial Notification Date 20 16 05 25

Notification time 10 00

1. Patient details

TasP ID

22 052

Name

T.P.

Sex

Male

Female

Date of birth

19 44 07 13

Enrolment date

20 14 07 28

2. Measurements

Height

100 Cms

Last known: Weight

66.4

Kgs

Weight Date

20 16 01 27

CD4 count

352

CD4 Date

20 15 08 31

Viral Load

< 40

Viral Load Date

20 15 08 31

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. Gastroenteritis 20 16 05 25

2.

3.

4.

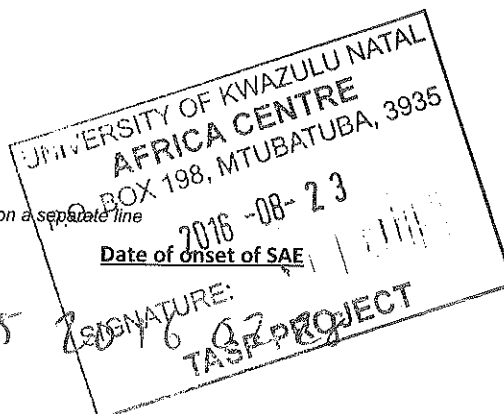
5.

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.

Unknown to TasP, patient was admitted to Ngqelizane hospital from 28/2/16 to 16/3/16 with gastroenteritis. She received IV fluids in hospital. Her renal function was impaired as a result of dehydration, and so TDF was changed to ABC. She reported this to TasP in May 2016. TasP will check her U+E and viral load. She can continue on ABC at present.



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. Atropin	1	PO	HIV	20140819	20160228	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. Hydrochlorothiazide	12.5mg	PO	hypertension	20140819		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						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

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

Patient is immunocompromised with increased risk of gastroenteritis. Risk of dehydration is high with gastroenteritis.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

☒ Recovered

A complementary SAE notification must be submitted within 8 days

Date of recovery

20160316

☒ Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE

Name

MEANIE HILL

Signature

[Signature]

Date form completed

20160525