



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ungulate Event, atypical events (my health for our health))

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00093242

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20140521

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140603

1. Patient details

TasP ID

24193

Name

M.M.

Sex

☒ Male

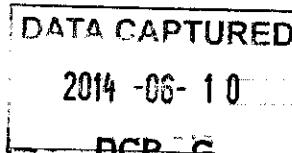
☐ Female

Date of birth

19540621

Enrolment date

20120417



2. Description of the reported SAE

Weight loss with dyspnoea

Date of SAE onset

20140519

3. Complementary information

Admitted to hospital on 22/05/2014 Diagnosed with
Acute gastroenteritis and pulmonary TB (GeneXpert
positive, Rifampicin sensitive)

4. New diagnosis?

☒ Yes → Describe

Acute gastroenteritis, PTB

No

Date of new diagnosis

20140523

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above
modified your judgement of causality regarding one or
more treatments compared to your initial notification?

☒ Yes → Section 6

No → Section 7

6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. ATRIPLA IDF/FTC/EFV	300/200/600	0.5	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

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

Acute gastroenteritis
Pulmonary TB.

8. SAE Outcome

Unknown to date ☐
☒ Ongoing ☐
Improved ☐
Worsened ☐
Recovered ☐

Another complementary SAE notification form must be submitted within 8 days from now.

Date of recovery

Recovered without sequelae
or
Recovered with sequelae
Describe

Physician reporting SAE Complementary Notification

Name

Collins Ignat

Signature

[Signature]

Date form completed

20140603