



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
(Urophila kwami, ukuphila kwethu (my health for our health))

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AC

v6 Feb 2, 12

Serious Adverse Event Reporting



00059994

ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

20130926

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140226

1. Patient details

TasP ID

29447

Name

NB

Sex

☐

Male

☒

Female

Date of birth

19930810

Enrolment date

20130926

2. Description of the reported SAE

Anaemia of chronic disease noticed at baseline

Date of SAE onset

UNKNOWN

3. Complementary information

Microcytic, hypochromic anaemia Secondary to  
Menorrhagia

Prescribed FeSO<sub>4</sub> and tranexamic acid.

Hb currently 8.8g/dL

4. New diagnosis?

☐ Yes → Describe

☒ No

Date of new diagnosis

11 FEB 2014

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☐ Yes

☐ No

☒ N/A

Which treatment?

Date discontinued

11 FEB 2014

b) Did the event reappear after reintroduction of treatment?

☐ Yes

☐ No

☒ N/A

Which treatment?

Date reintroduced

11 FEB 2014

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

DATA CAPTURE

2014-02-27

DCP - S

## 6. Medications

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

	<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
1.	TDF	300mg OD	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.	LAMIVUDINE	300mg	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.	EFAVIRENZ	300mg	OD	<input checked="" 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

ANAEMIA SECONDARY TO MENORRHAGIA.

## 8. SAE Outcome

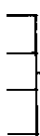
Unknown to date

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 Iwuji

Signature

Kinpin

Date form completed

20/4/2022