



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Uphila kwami, ukuphila kwethu)

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00059967

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

20130527

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130822

1. Patient details

TasP ID

21877

Name

T. B.

Sex

Male

☒ Female

Date of birth

19870825

Enrolment date

20130513

2. Description of the reported SAE

Grade 4 Anaemia - microcytic, hypochromic

Date of SAE onset

20130513

3. Complementary information

Anaemia secondary to heavy periods. Now resolved following treatment with ferrous sulphate. Hb is 12g/dL.

4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

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

DATA CAPTURE

2013-08-28

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. ✓	✓	✓	Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related 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

Menorrhagia causing Iron deficiency Anaemia

8. SAE Outcome

Unknown to date

Ongoing

Improved

Worsened

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

☒ Recovered

→ Date of recovery

Recovered without sequelae
or

Recovered with sequelae
→ Describe

Physician reporting SAE Complementary Notification

Name

COLLINS JWHJ1

Signature

[Signature]

Date form completed

20130822