



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC

22 May 2016



00596252

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

Complementary Notification Date 2016 0531

i.e. Date of original Initial Notification Form

1. Patient details

TasP ID

29103

Name

FM

Sex

Male

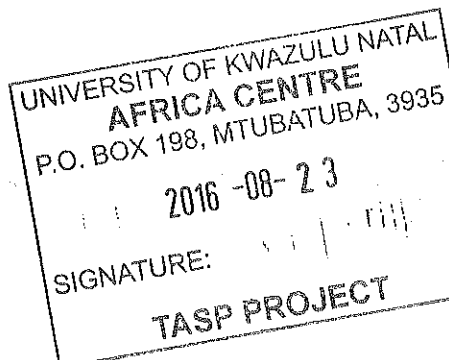
☒ Female

Date of birth

1968 01 21

Enrolment date

2013 05 28



2. Description of the reported SAE

Anaemia

Date of SAE onset

2015 04 13

3. Complementary information

linked to ABC/3TC/EFV on 10/6/2015
Hb improved from 4.9 to 8.9 g/dL on 29/9/2015

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

6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1.			<input 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? ☐ Yes ☒ No
 This includes the patient's medical history
 → Describe

8. SAE Outcome

☐ Death → Date of death _____ Probable Diagnosis _____
☐ Unknown to date
☐ Ongoing
☒ Improved → Another complementary SAE notification form must be submitted.
☐ Worsened
☐ Recovered → Date of recovery _____
☐ Recovered without sequelae
 or
☐ Recovered with sequelae
 → Describe

Physician reporting SAE Complementary Notification

Name

Signature

Date form completed

C. W. Smith
 20150531