



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

1st May 2015



00547563

## 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

20150519

i.e. Date of original Initial Notification Form

Complementary Notification Date

20151104

### 1. Patient details

TasP ID

52961

Name

Z.M.

Sex

Male

☒ Female

Date of birth

19870701

Enrolment date

20150416

### 2. Description of the reported SAE

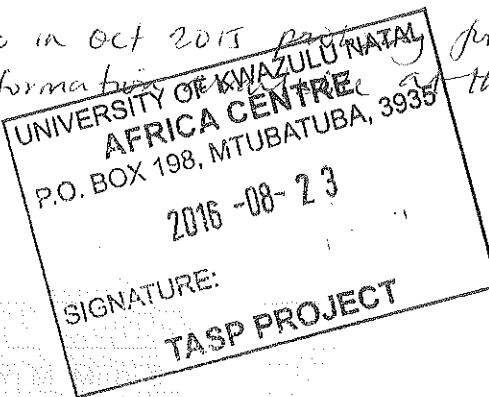
Known case of idiopathic thrombocytopenic purpura  
Previous multiple hospital admissions

Date of SAE onset

20150519

### 3. Complementary information

Readmitted to hospital in Oct 2015 for same  
reason. No further information at the moment



### 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. TDF/FTC/EFV	300/200/600	O.D.	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. PREPNISOLONE			<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

Idiopathic thrombocytopenic purpura. abnormal blood results predated enrolment in trial

## 8. SAE Outcome

Death → Date of death 21/11/2015 Probable Diagnosis

Unknown to date ☐

☒ Ongoing ☐ Improved ☐ Worsened ☐ Recovered

Another complementary SAE notification form must be submitted.

Recovered without sequelae ☐ or Recovered with sequelae ☐  
Describe

## Physician reporting SAE Complementary Notification

Name Collins Mary  
Signature Xmf  
Date form completed 20.11.15