



TasP

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

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Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00317359

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

2015 05 19

i.e. Date of original Initial Notification Form

Complementary Notification Date

2015 11 30

1. Patient details

TasP ID

52961

Name

Z. P. M.

Sex

Male

☒ Female

Date of birth

1983 07 01

Enrolment date

2015 04 16

Apologies, confusion over initial reporting date. It is 2015. Me.

2. Description of the reported SAE

Diagnosed with ITP, bleeding from gums, PV, PR. Admitted in hospital
17/4/15 - 5/5/15 and again 23/5/15 - 6/6/15

Date of SAE onset

2015 05 23

3. Complementary information

Admitted again due to ITP. She had missed her specialist appointments and it was unclear whether she was taking her steroids.

Self referred to Hlabisa feeling "weak" on 1/10/15. Found to be anaemic - Hb 3.4. Transferred to NGZ tertiary hospital. Transfused 4 units. Re-started steroids.

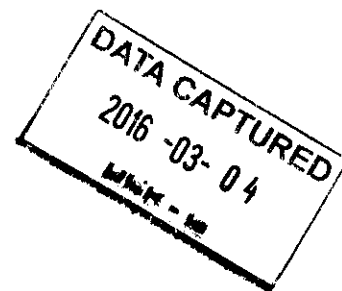
4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

Discharged on 18/11/15 with Hb 8.7, platelets 156.



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.			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 ☒

Describe

No ☐

Patient at risk of ITP regardless of participation in research.

8. SAE Outcome

Death → Date of death

Probable Diagnosis _____

Unknown to date

Ongoing

Improved

Worsened

→ Another complementary SAE notification form must be submitted.

☒ Recovered

→ Date of recovery 20151118

☒ Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature

[Signature]

Date form completed 20151130