

**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**

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ANRS 12249 Complementary SAE NotificationCompleted forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20141121

i.e. Date of original Initial Notification Form

Complementary Notification Date

20141210

1. Patient details

TasP ID

45243

Name

T.M.

Sex

☒ Male

Female

Date of birth

19820115

Enrolment date

20141015

2. Description of the reported SAE

The initial SAE was for hospitalisation between 3/11/14 to 8/11/14 for pancytopenia and severe immunosuppression (CD4 2). He also reported vomiting, that stopped in hospital. He had a blood transfusion, Steroids and fast-tracked ART in hospital.

Date of SAE onset 20141103

3. Complementary information

He was re-admitted to Hlabisa hospital on 17/11/14 with weakness, oral sores and nose/oral bleeding. On admission he was pyrexial, with distended abdomen, pancytopenia remained.

The plan was for a DIC screen, and discussion with a tertiary hospital as per entry on 24/11/14.

On 26/11/14 the plan was for blood transfusion. This was not given. On 30/11/14 he died.

No final diagnosis is recorded.

4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

DATA CAPTURE
2015 -01- 29
DCP - Z

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 ☒ No ☐

Describe

This patient was severely immunocompromised

8. SAE Outcome

● Death

→ Date of death

20141130

Probable
Diagnosis

Panmyelopenia

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae
or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature

[Signature]

Date form completed

20141210