



00199202

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

20140625

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140708

1. Patient details

TasP ID

22641

Name

T.M.

Sex

Male

☒ Female

Date of birth

19730708

Enrolment date

20130712

DATA CAPTURED
2014-07-23

2. Description of the reported SAE

Participant on AZT, 3TC, EFV. Presented with ~~hypotension~~ mild exertion, fatigue and palpitations. Full blood count taken - Hb 4.7 g/dL - Referred to hospital for transfusion.

Date of SAE onset 20140620

3. Complementary information

Participant admitted to Hlabisa hospital on 25/6/14; transfused 2 units of blood. Patient developed pancytopenia - Platelets 33; Hb 3.8; White Cell Count 3.38. Clinically deteriorated. CD4 count dropped from 102 to 22. Patient died after 11 days in hospital.

4. New diagnosis?

☒ Yes → Describe
☐ No

Pulmonary TB with pancytopenia

Date of new diagnosis 20140625

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

Patient had pulmonary TB + pancytopenia.
Continued to deteriorate after stopping ART.

8. SAE Outcome

● Death

→ Date of death

20140706

Probable
Diagnosis

Pulmonary TB + Pancytopenia.

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

M Hill

Date form completed 20140707