

ANRS 12249 Complementary SAE Notification

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



00317299

SAE No.

Initial Notification Date

20150519

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150615

1. Patient details

TasP ID

52961

Name

Z.P.M.

Sex

Male

☒ Female

Date of birth

19830701

Enrolment date

20150410

2. Description of the reported SAE

Participant admitted to hospital with CO_4 88% on ART. Haemoglobin was 3g/dl & Platelets 5. She was transfused & transferred to referral hospital where she was diagnosed with disseminated ~~DC~~ & re-initiated on ART.

Date of SAE onset 20150416

DATA CAPTURED

2015-08-18

3. Complementary information

Participant was reviewed at trial clinic; blood showed Hb 4, Sg/dl & Platelets 7. She was re-referred to hospital where she was admitted & transfused 4 units blood. She was transferred to referral hospital for further investigation. She was started on Prednisolone 60mg daily; and will be reviewed on 7/7/15. She was discharged on 6/6/15.

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.			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

Participant had longstanding history of abnormal bleeding. Recurrence of same problem; cause still being investigated.

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 DR GUGELIHE MKHULU

Signature

Date form completed 20150615