

Serious Adverse Event Reporting


00199220

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

20140929

i.e. Date of original Initial Notification Form

Complementary Notification Date

20141107

1. Patient details

TasP ID

29204

Name

S.N.N.

Sex

Male

☒ Female

Date of birth

19880923

Enrolment date

20130523

2. Description of the reported SAE

Participant on 70F/37C/EFV. incidentally discovered to be admitted to hospital on 24/9/2014. Diagnosed with Pulmonary TB and syphilis and started on treatment.

Date of SAE onset

20140905

3. Complementary information

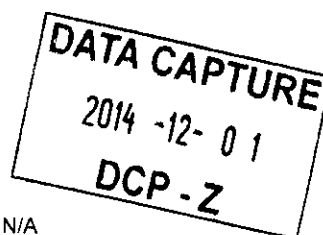
Hospital notes reviewed: Participant treated for syphilis; started on TB treatment. She was diagnosed with malnutrition & co-managed with dietician. She had anaemia, Hb 7.0 g/dl & transfused 1 unit blood. She improved & was discharged 6/10/2014 with plan to follow up at outpatients.

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

Patient with declining CD4 count + malnutrition - highly susceptible to infections.

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

Recovered without sequelae
or

☒ Recovered with sequelae

Describe Patient still on TB treatment.

Physician reporting SAE Complementary Notification

Name DR G. MUTHULISI

Signature

Date form completed 2014 10 10 7