



00059978

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

20130919

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130926

1. Patient details

TasP ID

30331

Name

M2B

Sex

Male

☒ Female

Date of birth

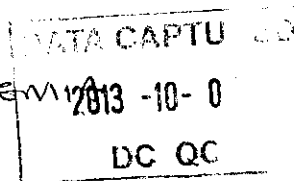
19940117

Enrolment date

20130711

2. Description of the reported SAE

CLINICALLY SYMPTOMATIC ANAEMIA



Date of SAE onset

UNKNOWN

3. Complementary information

Patient on treatment for TB lymph node since July 2013, referred to hospital on 17/9/2013 on account of symptomatic anaemia. She was admitted on 19/9/2013 and discharged on 24/9/2013, No blood transfusion given but patient feels much better.

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. Rifampin (Ritze)	3 tabs	daily	Unrelated Poss. related
Pyridoxine	25mg	daily	<input checked="" type="radio"/> Cannot be assessed
2. Tenofovir	300mg	daily	Unrelated Poss. related
Lamivudine	150mg	^{bid} daily	<input checked="" type="radio"/> Cannot be assessed
3. Efavirenz	600mg	daily	Unrelated Poss. related
4. FeSO ₄	200mg	tid	<input checked="" type="radio"/> Cannot be assessed 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

ANEMIA OF CHRONIC DISEASE.

8. SAE Outcome

Unknown to date
Ongoing
☒ Improved
Worsened
Recovered → Date of recovery

Another complementary SAE notification form must be submitted within 8 days from now.

Recovered without sequelae
or
Recovered with sequelae
→ Describe

Physician reporting SAE Complementary Notification

Name DR. ANTHONY A. OLIVE

Signature

Date form completed 20130926.