



00059966

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

20131001

1. Patient details

TasP ID

20331

Name

ZM

Sex

Male

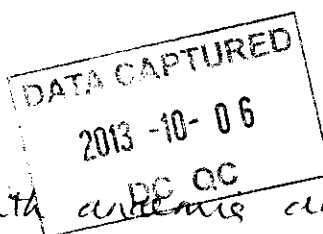
☒ Female

Date of birth

19940117

Enrolment date

20130715


2. Description of the reported SAE

Admitted to hospital with ~~anemia~~ and pulmonary TB.

Date of SAE onset

3. Complementary information

Readmitted 29/10/2013 with TB lymph node

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. RIFA FOUR	3 TABS PO	O.D	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. PYRIDOXINE	25mg PO	O.D	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. TENOFOVIR	300MG PO	O.D	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4. LAMIVUDINE	300MG PO	O.D	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
EFAVIRENZ	600MG PO	O.D	

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? Yes ☐ No ☒

This includes the patient's medical history

Describe

8. SAE Outcome

Unknown to date

☒ Ongoing

Improved

Worsened

Recovered → Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

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

Physician reporting SAE Complementary Notification

Name COLMAN / WUJ /

Signature Xmf

Date form completed 2013 01 01.