

Serious Adverse Event Reporting


00057339

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

20140117

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140314

1. Patient details

TasP ID

15664

Name

Ndlovu Fanyana F.N

Sex



Male

Female

Date of birth

19620620

Enrolment date

20130716

2. Description of the reported SAE

Referred to hospital with a suspected diagnosis of Pulmonary TB on 15/01/2014

Date of SAE onset

20131211

3. Complementary information

Was admitted to hospital for 3 weeks and started on treatment for pulmonary TB. Interrupted ART on discharge from hospital.

DATA CAPTURED

2014-03-17

DC QC

4. New diagnosis?
☒ Yes → Describe

Pulmonary tuberculosis

No

Date of new diagnosis

20140117

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

55482

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>	
1. TENOFOVIR	300MG	PO	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. LAMIVUDINE	300MG	PO	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. LOPINAVIR/ RITONAVIR	400/100	PO	O.D	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.				<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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
Describe

No
PULMONARY TB

8. SAE Outcome

Unknown to date
☒ Ongoing
 Improved
 Worsened
 Recovered

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

→ Date of recovery

Recovered without sequelae
 or
 Recovered with sequelae
 → Describe

Physician reporting SAE Complementary Notification

Name

COLUAS [WUJI]

Signature

Xinping

Date form completed

2014 0314