

Serious Adverse Event Reporting
Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu / my health, our health


00317352

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

20150121

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150331

1. Patient details

TasP ID

42864

Name

JT

Sex



Male

Female

Date of birth

19520304

Enrolment date

20141008

2. Description of the reported SAE

Diagnosed with Pulmonary TB on CXR, started TB treatment on 6/11/2014
she initiated Atripla on 24/11/2014 and developed dyspnoea &
wheeze. She was started on Prednisolone following this

Date of SAE onset 20141103

3. Complementary information

Prednisolone was started on 11/12/2014 and stopped on 16/12/2014

4. New diagnosis?

Yes → Describe

☒ No

71

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. RHZE		od	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. ATRIPLA	T	od	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. PREDNISOLONE	20mg	od	<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? ☒ Yes ☐ No
 This includes the patient's medical history ☐ Describe

8. SAE Outcome

- ☒ Death → Date of death 20150117 Probable Diagnosis TB.
- Unknown to date ☐
- Ongoing ☐
- Improved ☐
- Worsened ☐
- Recovered → Date of recovery
- Recovered without sequelae
- or
- Recovered with sequelae
- ☐ Describe

Physician reporting SAE Complementary Notification

Name COLIN S. Iwaji

Signature *Xmp*

Date form completed 20150408