

**Serious Adverse Event Reporting**


00317312

**ANRS 12249 Complementary SAE Notification**

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20160404

i.e. Date of original Initial Notification Form

Complementary Notification Date

20160603

**1. Patient details**

TasP ID

46643

Name

T. S. G.

Sex

Male

☒ Female

Date of birth

19650507

Enrolment date

20150309

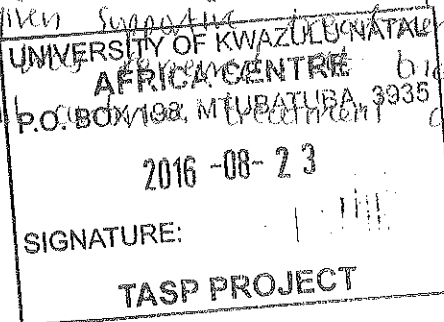
**2. Description of the reported SAE**

Participant on Atripla; CD4 count 353; viral load <40. She presented to clinic with TB symptoms; sputum was taken. Results showed MDR-TB. She was admitted to hospital on 04/04/2016 for treatment.

Date of SAE onset 20160323

**3. Complementary information**

Participant was started on MDR-TB treatment on 04/04/2016. She responded well to treatment. She was given supportive treatment by dietician. She was discharged on 2016/04/22. She was followed up at local clinic on 02/06/2016. She is clinically well. She will continue treatment at local clinic.


**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

Participant susceptible to TB due to immunosuppression.

## 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 2016 04 22

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Patient on MDR-TB treatment.

## Physician reporting SAE Complementary Notification

Name GUG'ELIHE WIKHULU

Signature

Date form completed 2016 06 03