

**Serious Adverse Event Reporting**


00317362

**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

2015 10 30

*i.e. Date of original Initial Notification Form*

Complementary Notification Date

2015 12 17

**1. Patient details**

TasP ID

S 2 9 5 2

Name

Z.A.M.

Sex

Male

☒ Female

Date of birth

19 88 01 29

Enrolment date

20 15 04 15

**2. Description of the reported SAE**

Diagnosed with rifampicin resistant TB on Sputum GXP.  
Referred to Hlabisa hospital for initiation of treatment.  
Was ART naive at time of MDR diagnosis.

Date of SAE onset

2015 10 12

**3. Complementary information**

This patient was admitted from Hlabisa

She was discharged in early December

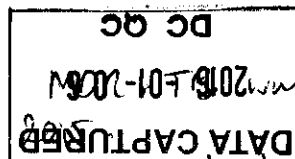
She was seen in TasP clinic 10/12/15 initiated,

MDR treatment will continue for a total 18 months.

but apparently asymptomatic.

She was also initiated

on TDF/FTC/EFV as an inpatient.


**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

Patient immunocompromised as at risk of MDR TB.

## 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 20151210

☒ Recovered without sequelae  
or

Recovered with sequelae

Describe

## Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature 

Date form completed 20151217