

Serious Adverse Event Reporting


00317301

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

20150804

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150817

1. Patient details

TasP ID

24250

Name

S.N.G.

Sex



Male

Female

Date of birth

19560306

Enrolment date

20130405

2. Description of the reported SAE

Participant not yet on ART. Newly diagnosed with MDR-TB on sputum
and admitted to hospital for initiation of treatment.

Date of SAE onset

20150731

3. Complementary information

Review of hospital notes: Participant admitted with chest pain & cough. He
was started on MDR-TB treatment which he tolerated well. He was
discharged on 07/08/2015 and will be followed up at local clinic
to be initiated on ART.

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 Pre-ART therefore susceptible to TB. MDR-TB highly prevalent in subdistrict.

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

Recovered without sequelae
or

☒ Recovered with sequelae

Describe Participant on MDR-TB treatment.

Physician reporting SAE Complementary Notification

Name DR GUG'ELILE MKHULISI

Signature

Date form completed 20150817