

Serious Adverse Event Reporting


00199215

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

2014 08 26

i.e. Date of original Initial Notification Form

Complementary Notification Date

2014 09 15

1. Patient details

TasP ID

32824

Name

J.K.M.

Sex

Male

☒ Female

Date of birth

1975 02 15

Enrolment date

2014 08 18


2. Description of the reported SAE

The patient had renal failure on her baseline TasP blood tests - for which she was referred to Hlabisa hospital, and TDF was stopped. At Hlabisa she was also diagnosed with a lower respiratory tract infection and given IV antibiotics. She was discharged on 29/8/14.

Date of SAE onset

2014 08 19

3. Complementary information

She was reviewed at TasP clinic on 15/9/14. She was unwell; tachycardic; weak; coughing with reduced air entry right base of lung. Respiratory rate at rest was 34. She was re-referred back to Hlabisa with a probable diagnosis of pulmonary tuberculosis. (Recent creatinine levels are unknown)

4. New diagnosis?
☒ Yes → Describe

Probable Pulmonary Tuberculosis

No

Date of new diagnosis

2014 09 15

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?

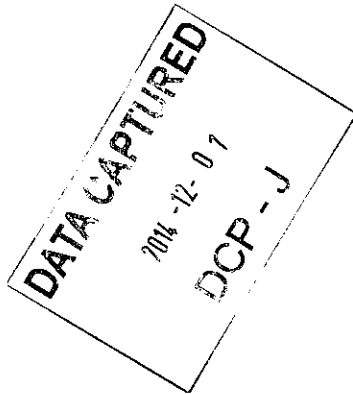
Yes → Section 6

☒ 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

Renal failure was present at baseline.
The patient is immunocompromised with high risk of opportunistic infections.

8. SAE Outcome

Death → Date of death

Unknown to date

☒ Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Probable

Diagnosis _____

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature [Signature]

Date form completed 2014 09 15