

Serious Adverse Event Reporting


00199219

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 30

1. Patient details

TasP ID

32824

Name

J.K.M.

Sex

Male

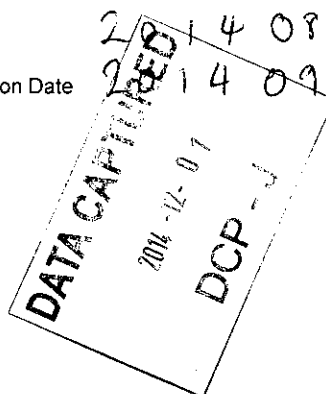
☒ Female

Date of birth

1975 02 15

Enrolment date

2014 08 18


2. Description of the reported SAE

This patient initially had renal failure. She was admitted to hospital + TDF stopped. In hospital she was also treated for a lower respiratory tract infection. After discharge she deteriorated with cough tachypnoea + weakness. She was re-referred on 15/9/14 with probable tuberculosis.

Date of SAE onset 2014 08 19

3. Complementary information

Hlabisa hospital diagnosed a pleural effusion - extra pulmonary TB. She had a pleuritic tap in their outpatient department and sent home on the same day with TB treatment. Although she was referred to hospital she was not admitted. TasP clinic staff report that she is improving in the community.

4. New diagnosis?
☒ Yes → Describe

Extra-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?

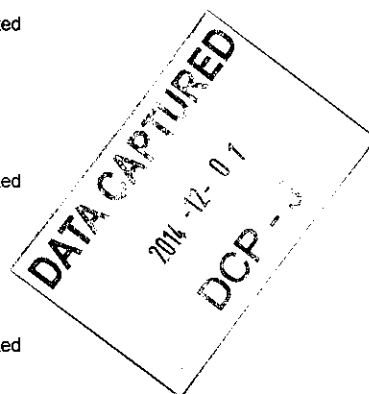
Yes → Section 6

☒ 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

The patient is immunocompromised with high risk of opportunistic infections.

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 2014 09 30 error Max

☒ Recovered without sequelae
or

Recovered with sequelae

Describe

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature *M Hill*

Date form completed 2014 09 30