

Serious Adverse Event Reporting


00057201

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

20130409

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130517

1. Patient details

TasP ID

16372

Name

P. M.

Sex

☒ Male

☐ Female

Date of birth

19611125

Enrolment date

20120925

2. Description of the reported SAE

PULMONARY MDR-TB : STARTED TREATMENT 2013/04/09

Date of SAE onset

20130409

3. Complementary information

DISCHARGED FROM HOSPITAL 2013/05/07 CONTINUING TREATMENT
ON AMBULATORY BASIS WITH INJECTABLE ANTI-TB AGENTS x 5/WK AT
CLINIC. TREATING

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. TENORMIN EMILICITABINE EFMAEN 2	1 tab nocte	nocte	<input checked="" type="checkbox"/> 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? ☒ Yes ☐ No
This includes the patient's medical history
 Describe TB DISEASE

8. SAE Outcome

Unknown to date
 Ongoing
☒ Improved
 Worsened
 Recovered

→ Another complementary SAE notification form must be submitted within 8 days from now.

→ Date of recovery

Recovered without sequelae
 or
 Recovered with sequelae
 Describe

Physician reporting SAE Complementary Notification

Name RICHARD JESSELL

Signature *Richard Jessell*

Date form completed 20130517