

Serious Adverse Event Reporting


00093243

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

20140529

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140617

1. Patient details

TasP ID

27506

Name

D.D

Sex

☒ Male

Female

Date of birth

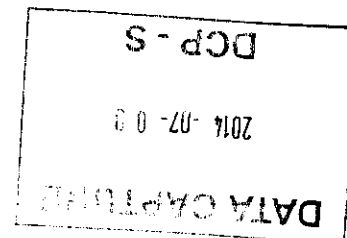
19701124

Enrolment date

20130319

2. Description of the reported SAE

Abnormal LFTs, abd pain and fever.
Diagnosed with Acute cholecystitis



Date of SAE onset

20140527

3. Complementary information

Diagnosed with Pulmonary tuberculosis on 03/06/2014
Sputum Genexpert showed drug sensitive MTB complex.
LFTs have remained abnormal since Baseline clinic visit
and have continued to fluctuate.

4. New diagnosis?
☒ Yes → Describe

Pulmonary tuberculosis

No

Date of new diagnosis

20140603

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

PULMONARY TUBERCULOSIS

8. SAE Outcome

Unknown to date ☐
☒ Ongoing ☐ → Another complementary SAE notification form must be submitted within 8 days from now.
 Improved ☐
 Worsened ☐
 Recovered ☐ → Date of recovery

Recovered without sequelae
 or
 Recovered with sequelae
 → Describe

Physician reporting SAE Complementary Notification

Name

COLLINS, THUY

Signature

[Signature]

Date form completed

20140617