

Serious Adverse Event Reporting



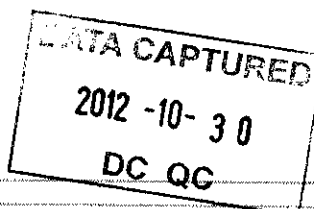
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ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No. _____ Initial Notification Date 20120921 i.e. Date of original Initial Notification Form
Complementary Notification Date 20121024

1. Patient details
TasP ID 14934
Name _____
Sex ☒ Male ☐ Female
Date of birth 19840502
Enrolment date 20120821



2. Description of the reported SAE
PHYSICAL ASSAULT

Date of SAE onset 20120902

3. Complementary information
STAB INJURY RIGHT CHEST. RESULTED IN A HAEMOTHORAX. ADMITTED TO HOSPITAL ON 04/09/2012. DEVELOPED EMPYEMA WHILE HAEMOTHORAX WAS BEING DRAINED. REFERRED TO THORACIC CLINIC FOR FURTHER MANAGEMENT. EMPYEMA DRAINED, NOW RESIDUAL (R) PLEURAL EFFUSION

4. New diagnosis?
☒ Yes → Describe POST-TRAUMATIC (R) EMPYEMA THORACIS
☐ No
Date of new diagnosis 20120809

5. Patient treatment

a) Did the event resolve after discontinuation of treatment? ☐ Yes ☐ No ☒ N/A
→ Which treatment? _____
Date discontinued Y Y Y Y M M D D

b) Did the event reappear after reintroduction of treatment? ☐ Yes ☐ No ☒ N/A
→ Which treatment? _____
Date reintroduced Y Y Y Y M M D D

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. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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: PHYSICAL ASSAULT

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 [Y.Y.Y.Y, M.M.D.D.]

☐ Recovered without sequelae
or
☐ Recovered with sequelae
Describe: _____

Physician reporting SAE Complementary Notification

Name RICHARD LESSELLS

Signature [Signature]

Date form completed 20121024