

Serious Adverse Event Reporting


00317302

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

20150804

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150817

1. Patient details

TasP ID

44537

Name

E.K.M.

Sex

Male

☒ Female

Date of birth

19440802

Enrolment date

20140915

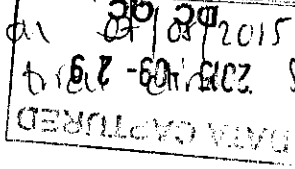
2. Description of the reported SAE

Participant on Atripla; CD4 count 196 and undetectable viral load.
Relative reported she had been diagnosed with breast cancer and
admitted to hospital on 08/08/2015.

Date of SAE onset 20150803

3. Complementary information

Participant had right mastectomy done on 04/08/2015. She
was discharged from hospital on 08/08/2015. She is being
followed up at hospital and stable. She is currently stable.


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.			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

Participants age + immune status are risk factors for cancer.

8. SAE Outcome

Death → Date of death Probable Diagnosis _____

Unknown to date

Ongoing

Improved

Worsened

Recovered → Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe Participant has had mastectomy.

Physician reporting SAE Complementary Notification

Name DR GUGLIELMO MICHULISI

Signature

Date form completed 20150817