

Serious Adverse Event Reporting
ANRS 12249 Initial SAE Notification

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002



00317467

SAE No.

SAE Visit Date

20151007

Initial Notification Date

20151020

Notification time

0950

1. Patient details

TasP ID

41682

Name

M.B.M.

Sex

Male

Female

Date of birth

19590211

Enrolment date

20140209

2. Measurements

Height

UUU Cms

Last known: Weight

61.9

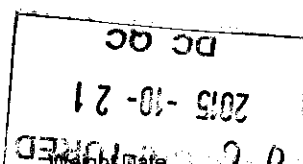
Kgs

CD4 count

808

Viral Load

<40



Weight Date

20151007

CD4 Date

20150120

Viral Load Date

20150327

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☐ Resulted in death → Date of death Probable cause
- ☐ Life threatening (i.e. at risk of death at time of event)
- ☐ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital abnormality / birth defect
- ☐ Grade 4 clinical and biological events
- ☒ Other serious, medically-important condition → Specify **Metastatic Breast Cancer**

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name

Date investigator
became aware

Date of onset of SAE

1. Metastatic Breast Cancer 20151007 20130000

2.

3.

4.

5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

Patient known to have breast cancer prior to TasP (treated in 2013 with left mastectomy, chemo + radio-therapy). She was told that she has metastases in the liver. (Primary) She has stopped engaging with health services for her breast cancer, as she knows she has a terminal illness. She is deteriorating, with an infected left chest wall and what looks like secondaries on the right breast. She now declines ART and wishes to exit TasP. Exit form written.

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. PATIENT STOPPED TAKING HER PRESCRIBED ART IN JUNE 2015!						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt Stop

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

Patient had breast cancer before the trial. Unfortunately it has progressed.

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days →

Patient has exited TAP
So no further SAE will be done.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 20151020