

Serious Adverse Event Reporting
ANRS 12249 Initial SAE Notification


00125385

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

SAE No.

SAE Visit Date

20141016

Initial Notification Date

20141114

Notification time

1600

1. Patient details

TasP ID

41714

Name

S.M.W.

Sex

Male

☒ Female

Date of birth

19651005

Enrolment date

20140925

2. Measurements

Height

Cms

Last known: Weight

63.9

Kgs

Weight Date

20141016

CD4 count

497

CD4 Date

20140925

Viral Load

86093

Viral Load Date

20140925

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

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

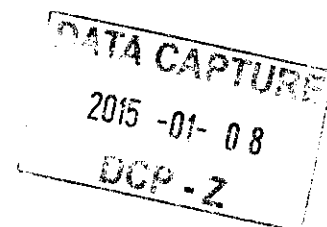
1. Acute psychosis 20141113 20141010

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.

Participant newly enrolled in trial, not yet on ART. Presented with 1 week history of psychotic symptoms and an enquiry revealed a longstanding history of depressive symptoms. She was referred to hospital for investigation. She was admitted for 3 days (27/10/14-31/10/14) for investigation & diagnosed with Major Depressive disorder with psychotic features and was started on treatment.

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.						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	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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? ☒ Yes ☐ No
This includes the patient's medical history

Describe

Patient had longstanding history of undiagnosed depression which complicated with psychosis.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered → Date of recovery

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Patient on Fluoxetine + Risperidone.

Physician reporting SAE

Name DR GUG'ELIHE MUKHULISI

Signature

Date form completed 20141114