

Serious Adverse Event Reporting



00317307

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

20160212

I.e. Date of original Initial Notification Form

Complementary Notification Date

20160301

1. Patient details

TasP ID

49362

Name

Z.D.

Sex

Male

☒ Female

Date of birth

19880305

Enrolment date

20150623

2. Description of the reported SAE

Trial participant on Atripla; CD4 count 141, viral load 322572. Reported to have been admitted to hospital with severe acute malnutrition. She had been diagnosed with malnutrition.

Date of SAE onset 20160121

3. Complementary information

Participant discharged on 18/02/2016. Discharge letter states she was treated for severe acute malnutrition. She was discharged with Virological failure as viral load was >1000 & switched to Atripla (Lamivudine). She will be followed up at TASP PROJECT.

4. New diagnosis?

☒ Yes → Describe

No

Virological failure

Date of new diagnosis 20160218

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

No

N/A

Which treatment?

Atripla stopped. Participant now on second line regimen.

Date discontinued

20160211

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

Participant with treatment failure. Immunosuppression may pre-dispose her to malnutrition

8. SAE Outcome

Death → Date of death

Probable Diagnosis _____

Unknown to date

Ongoing

Improved

Worsened

→ Another complementary SAE notification form must be submitted.

☒ Recovered

→ Date of recovery 20160218

Recovered without sequelae

or

☒ Recovered with sequelae

Describe

Now on second line regimen.

Physician reporting SAE Complementary Notification

Name GUG'ELILE MUKHULISI

Signature

Date form completed 20160301