



00317462

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

SAE No.

SAE Visit Date

20150923

Initial Notification Date

20150923

Notification time

16 00

1. Patient details

TasP ID

34422

Name

S.B.M.

Sex

☒

Male

Female

Date of birth

19820328

Enrolment date

20131203

2. Measurements

Height

165

Cms

Last known: Weight

42.0

Kgs

Weight Date

20150923

CD4 count

32

CD4 Date

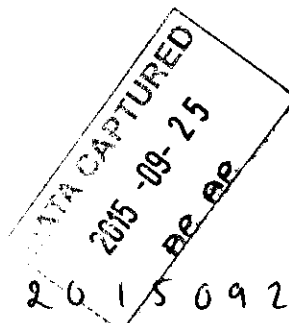
20150921

Viral Load

<40

Viral Load Date

20140915


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. ?TB 20150923 20150823
2. Urinary tract infection 20150923 20150919
- 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 defaulted ART since Jan 2015. Returned to clinic c/o cough, night sweats, weight loss, vomiting for 1 month, and 4 day history of dark urine.

At clinic (23/9/15) BP = 114/84, HR 108, urine dip: leukocytes 1+, protein 3+, blood 2+, ketones 3+. Given ketones in urine + patient vomiting, patient referred to Alabisa Hospital for blood tests, CXR, UTI treatment, rehydration + dietitian review.

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. Not on any drugs: Defaulted.						Unrelated	Yes	None
2.						Poss. related	No	Reduce
3.						Cannot be assessed		Interrupt Stop
4.						Unrelated	Yes	None
5.						Poss. related	No	Reduce
6.						Cannot be assessed		Interrupt Stop
7.						Unrelated	Yes	None
8.						Poss. related	No	Reduce
9.						Cannot be assessed		Interrupt Stop
10.						Unrelated	Yes	None
11.						Poss. related	No	Reduce
12.						Cannot be assessed		Interrupt Stop
13.						Unrelated	Yes	None
14.						Poss. related	No	Reduce
15.						Cannot be assessed		Interrupt Stop
16.						Unrelated	Yes	None
17.						Poss. related	No	Reduce
18.						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?

This includes the patient's medical history

Yes ☒ No ☐
Describe

Patient has been lost to TASP for 9 Months. Only returned now as he is sick.

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name MELANIE Hill

Signature 

Date form completed 2015 09 23