

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



00317418

SAE No.

SAE Visit Date

20150901

Initial Notification Date

20150904

Notification time

1630

1. Patient details

TasP ID

47134

Name

S.K.D.

Sex



Male

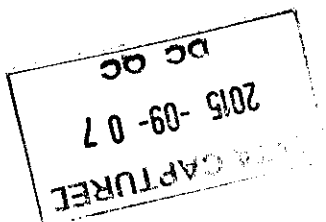
Female

Date of birth

19730711

Enrolment date

20141010


2. Measurements

Height

162 Cms

Last known: Weight

56.1

Kgs

Weight Date

20150817

CD4 count

323

CD4 Date

20150625

Viral Load

499365

Viral Load Date

20150625

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. Pulmonary TB 20150904 20150902

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 in intervention arm. At baseline, CD4 count 323 & viral load 499365, not yet on ART. Full blood count showed Hb 9.5g/dl & Platelets 1. He was seen by trial clinician; was clinically well. FBC repeated; Hb 8.4 g/dl & platelets 5. He was suspected to have idiopathic thrombocytopenic purpura. He developed haemoptysis; Genexpert was negative in sputum & he was confirmed TB positive on chest xray at hospital. He was admitted on 2/4/15 to start treatment. More information to follow on discharge.

6. Medications

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

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</u>	<u>Indication</u>	<u>Date started</u> <u>Date stopped</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
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		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

Participant already had TS symptoms at baseline.

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 GUGLIELMO MUKHULISI

Signature

Date form completed 20150904