



TasP

Authorised Treatment as Prevention - ANRS 12249
Urophila Events, Adverse Events (see health for our health)

Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

Mchatswini

SAE-AI

131 Jan 2013

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

00093269

SAE No.

SAE Visit Date

20131019

Initial Notification Date

20131024

Notification time

1. Patient details

TasP ID

25883

Name

DB

Sex

☐ Male

☒ Female

Date of birth

19661129

Enrolment date

20130326

DATA CAPTURED

2013-11-01

DOP-J

2. Measurements

Height

164 Cms

Last known: Weight

94.0

Kgs

Weight Date

20131019

CD4 count

497

CD4 Date

20131019

Viral Load

Viral Load Date

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. ANAEMIA 20131024 20131019

2. Y Y Y Y M M D D Y Y Y Y M M D D

3. Y Y Y Y M M D D Y Y Y Y M M D D

4. Y Y Y Y M M D D Y Y Y Y M M D D

5. Y Y Y Y M M D D Y Y Y Y M M D D

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.

Routine FBC showed an HB of 6.1 g/dL, mcv 64.7
MCH 17.9. This suggests iron deficiency anaemia. Patient is
in the control arm of the trial and not eligible for ART.

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		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

Probable Iron deficiency Anaemia

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted with the SAE

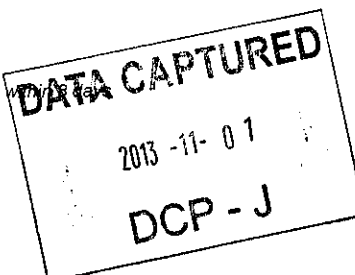
→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe



Physician reporting SAE

Name

COLLINS Iwan J

Signature

[Handwritten signature]

Date form completed

20131024