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

SAE No.

SAE Visit Date

20140204

Initial Notification Date

20140205

Notification time

1100

1. Patient details

TasP ID

15178

Name

~~Khalek~~ Khalek Zwane K.Z.

Sex

☒ Male

☐ Female

Date of birth

19870602

Enrolment date

20120920

2. Measurements

Height

165 Cms

Last known: Weight

60.7

Kgs

Weight Date

20140204

CD4 count

224

CD4 Date

20131007

Viral Load

111

Viral Load Date

20131007

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

Fracture right wrist

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.

Fracture Rt
wrist

20140204

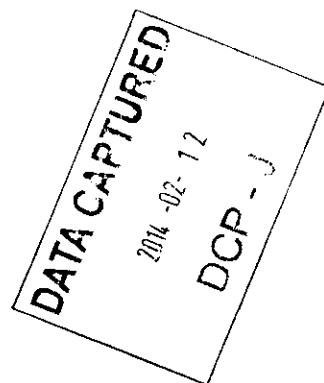
20131225

2.

3.

4.

5.



5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

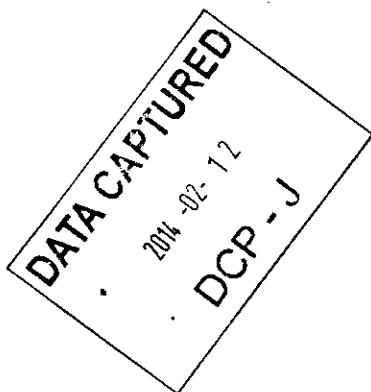
Attach copies of any relevant hospital records, laboratory test results etc.

Fall from a height and injured his right arm. Sustained a fracture to his right wrist and bruised his left foot

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. ATRIPLA TDF/FTC/EFV	300/200/600	PO	HIV	20121017		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
2. COTRIMOXAZOLE			PROPHYLAXIS	20120920		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		Inter 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

ACCIDENT

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20140128

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name

COLUMS IWNJ1

Signature

Xup

Date form completed

20140205