

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
Ukaphila kwami, ukaphila kwethu (my health for my health)**Ukaphila kwami, ukaphila kwethu****Africa Centre TasP Trial****SAE-AC****Serious Adverse Event Reporting**

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ANRS 12249 Complementary SAE NotificationCompleted forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20151009

i.e. Date of original Initial Notification Form

Complementary Notification Date

20151114

1. Patient details

TasP ID

46658

Name

DM

Sex

Male

☒ Female

Date of birth

19791203

Enrolment date

20141119

2. Description of the reported SAE

On treatment for TB spine with RHZE. Found to be jaundiced on routine clinic appointment and referred to hospital. TB treatment was discontinued. Provisional diagnosis was drug induced liver injury

Date of SAE onset 20151001

3. Complementary information

Patient admitted to hospital. TB treatment was discontinued. On 9/10/2015 TBil 116, ConBil 77 ALT 231, ALP 83, GGT 154; 15/10: TBil 42, ALT 56 ALP 87 GGT 183. Patient was restarted on TB Rx by hospital & discharged when followed up on 2/11/2015; TBil 229, ConBil 136, ALT <5, ALP 91, GGT 84. Advised by trial team to stop TB Rx & call an ambulance. Re-admitted to hosp on 5/11/2015 and died on 28/11/2015

4. New diagnosis?

Yes → Describe

☒ No

Drug induced liver injury resulting in death

Date of new diagnosis

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

No

N/A

Which treatment?

improve L

Date discontinued

20151008

b) Did the event reappear after reintroduction of treatment?

☒ Yes

No

N/A

Which treatment?

TB treatment

Date reintroduced

will need hospital notes

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**DATA CAPTURED**

2016-03-04

BGP - G

6. Medications

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

| Generic Name | Dose | Frequency | New judgement of causality |
|------------------------------|------|-----------|--|
| 1. AS listed in initial SAE. | | | 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

Drug induced Liver injury from TB.

8. SAE Outcome

☒ Death → Date of death 20151108 Probable Diagnosis Drug induced Liver injury

☐ Unknown to date

☐ Ongoing

☐ Improved

☐ Worsened

☐ Recovered → Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

Another complementary SAE notification form must be submitted.

Physician reporting SAE Complementary Notification

Name COLLINS WUJI

Signature *[Signature]*

Date form completed 20151114