



00125391

SAE No.

SAE Visit Date

20 14 10 23

Initial Notification Date

20 14 11 28

Notification time

11 00

1. Patient details

TasP ID

33709

Name

J. B. Z.

Sex



Male

Female

Date of birth

1972 01 13

Enrolment date

20 14 09 02

2. Measurements

Height

167

Cms

Last known: Weight

58.8

Kgs

Weight Date

20 14 10 23

CD4 count

791

CD4 Date

20 14 09 30

Viral Load

29392

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

20 14 11 04

Probable cause

Dry Induced liver failure



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

- | Event Name | Date investigator became aware | Date of onset of SAE |
|------------------|--------------------------------|----------------------|
| 1. Liver failure | 20 14 10 23 | 20 14 09 30 |
| 2. Pulmonary TB | 20 14 10 23 | 20 14 09 07 |
| 3. Diarrhoea | 20 14 10 23 | 20 14 09 07 |
| 4. Pedal Oedema | 20 14 10 23 | 20 14 09 07 |
| 5. | | |

DATA CAPTURE

2015 -01- 09

DCP - S

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.

The patient transferred into TasP already on PTB treatment, but was ART naive. Clinic baseline bloods showed ALP 116; AST (754); ALT (497). He was reviewed by the TasP doctor on 23/10/14. He had multiple problems including diarrhoea, bilateral pitting pedal oedema + weakness - present since the TB diagnosis on 7/9/14. At this point he was not jaundiced. He was referred to Alabisa hospital on 23/10/14 with a presumed drug induced liver injury. He died on 4/11/14.

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.	R.H.Z.E	4 tablets	PO	TB	2014 09 07	2014 10 23	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes No	None Reduce Interrupt Stop
2.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce 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

The patient was already on TB treatment prior to enrollment in TAP.

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 2014 11 28