

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. ATRIFLA TDF/FR/EFV	300/200/600	PO	HIV	20130611	20130712	Unrelated ● Poss. related Cannot be assessed	● Yes No	None Reduce Interrupt ● Stop
2. PYRIDOXINE	25mg	PO	PROPHYLAXIS FOR PERIPHERAL NEUROPATHY	20130501		Unrelated Poss. related Cannot be assessed	Yes ● No	None Reduce Interrupt Stop
3. ISONIAZID	300mg	PO	TB PROPHYLAXIS	20130501		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? ☐ Yes ☒ No
This includes the patient's medical history ☐ Describe

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

Signature

Date form completed

COLLINS 14/07/16

[Signature]

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