



00317351

ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

20150311

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150331

1. Patient details

TasP ID

44446

Name

D.S.

Sex

☒ Male

Female

Date of birth

19481024

Enrolment date

20141112

2. Description of the reported SAE

Death due to congestive cardiac failure

Date of SAE onset

20150217

3. Complementary information

Participant was on Atripla (TDF/FTC/EFV) prior to enrolment in trial (but did not disclose this information). CrCL was 62ml/min at baseline trial clinic visit and remained normal when admitted to hospital for congestive cardiac failure. He was started on furosemide in hospital, developed hyponatraemia & acute renal failure and died.

4. New diagnosis?
☒ Yes → Describe

hyponatraemia + Acute renal failure secondary to diuretic therapy.

No

Date of new diagnosis

20150302

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

Date reintroduced

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

6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. Furosemide	40mg BID		<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. ATRIPLA	T O A		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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

diuretic therapy for congestive cardiac failure resulting in hyponatremia and acute renal failure

8. SAE Outcome

☒ Death

→ Date of death

20150302

Probable
Diagnosis

Hyponatremia / Acute renal failure

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name

COLENS Jwaji

Signature

Kmp

Date form completed

20150408