

Serious Adverse Event Reporting


00199208

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 20 14 07 03 i.e. Date of original Initial Notification Form
Complementary Notification Date 20 14 08 06

1. Patient details

TasP ID 29835
Name S.N.
Sex Male ☒ Female
Date of birth 19 85 12 31
Enrolment date 20 13 09 03

2. Description of the reported SAE

Participant with MDR-TB on treatment. Discharged from hospital after 6 month stay. Presented with progressive fatigue, general weakness & loss of weight. Was unable to walk. Severely emaciated with weight 34kg. Referred to hospital.
Date of SAE onset 20 14 06 11

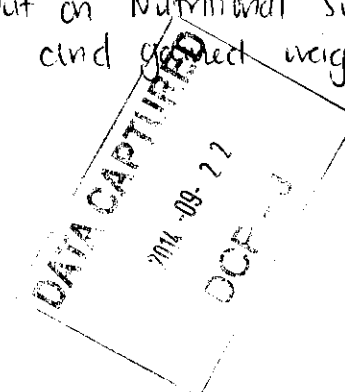
3. Complementary information

Participant was admitted, diagnosed with severe acute malnutrition. She was co-managed with dietician. She was put on Nutritional Supplements and weight monitoring. She improved clinically and gained weight. Was discharged after 1 month stay.

4. New diagnosis?

☒ Yes → Describe Severe Acute Malnutrition
No

Date of new diagnosis 20 14 07 04


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?

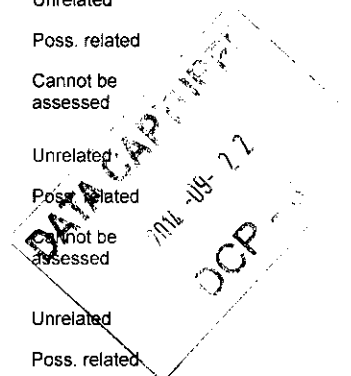
Yes → Section 6

☒ No → Section 7

6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1.			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? ☒ Yes ☐ No
This includes the patient's medical history

Describe Pt severely ill with comorbid MDR-TB and advanced HIV disease. She has poor social circumstances and poor nutrition.

8. SAE Outcome

Death → Date of death Probable Diagnosis _____
 Unknown to date _____
 Ongoing _____
 Improved → Another complementary SAE notification form must be submitted.
 Worsened _____
☒ Recovered → Date of recovery

Recovered without sequelae
 or
☒ Recovered with sequelae
 Describe Patient still undergoing outpatient management of Malnutrition.

Physician reporting SAE Complementary Notification

Name GUGELIHE NIKHILINI

Signature

Date form completed 20140806