Acrostic acrostic

Participant ID pid | MSO compby | V.C. vc

Date of Report vis_mth / vis_day / vis_yr

Event Evaluation

(To be completed by Medical Safety Officer)

Date of Event: evnt_dat_eevl (mm/dd/yyyy)

Source: source_eevl
-9
1 Masked
2 Unmasked
3 Both
4 New Report
5 Follow-Up Report
-6 Not on form

Provide a short description of the event:

eventdesc_eevl

Review event and determine whether any of the following criteria apply:

1. Criteria for Serious Adverse Events

A. Acute life threatening — lifethrt_eevl
-9
1 Yes (Go to 3A)
0 No
-6 Not on form

B. Results in prolonged, permanent severe disability — sevdisab_eevl
-9
1 Yes (Go to 3A)
0 No
-6 Not on form

C. A severe illness, or accident (includes worsening of a pre-existing injury) — sevillns_eevl
-9
1 Yes (Go to 3A)
0 No
-6 Not on form

D. Inpatient hospitalization, surgical procedure, or treatment to prevent a serious event — inphosp_eevl
-9
1 Yes (Go to 3A)
0 No
-6 Not on form

E. Event resulted in death — death_eevl
-9
1 Yes (Go to 3A)
0 No
-6 Not on form

2. Does not meet the criteria of serious but is unexpected. notser_eevl

3. Relationship to Intervention

A. What is the causal relationship between the adverse event and the intervention? (X one that applies)

1. Definite - Temporal pattern + Known or expected AE response pattern + Confirmed by stopping the intervention + Reappearance of AE on re-challenge — relint_eevl value="1"

2. Probable - Temporal pattern + Known or expected AE response pattern + Confirmed by stopping the intervention + Could not be explained by participant?s clinical state — relint_eevl value="2"

3. Possible - Temporal pattern + Known or expected AE response pattern + Could have been produced by a number of other factors — relint_eevl value="3"

4. Unknown - Relationship for which no evaluation can be made — relint_eevl value="4"

5. Not Related - AE for which sufficient information exists to indicate that the cause is unrelated to the study intervention — relint_eevl value="5"

4. Has the intervention been interrupted or stopped in relation to this adverse event? intstop_eevl
-9
1 Yes
0 No

-6 Not on form

sdeff_eevl

5. Has the participant experienced other intolerable side effects or symptoms and requested suspension or reduction of the study?

-9
1 Yes (specify)
0 No
-6 Not on form

Please specify what the side effect was and if the study intervention was discontinued:

sdeddsp_eevl

listprot_eevl

6. Was the adverse event(s) listed in the protocol?

-9
1 Yes
0 No (specify)
-6 Not on form

Please specify unlisted event:

unlistd1_eevl

listinfc_eevl

7. Was the adverse event(s) listed in the informed consent?

-9
1 Yes
0 No (specify)
-6 Not on form

Please specify unlisted event:

unlistd2_eevl

chngprot_eevl

8. Should a change in the protocol be considered to reduce or eliminate risk to subjects?

-9
1 Yes
0 No (specify)
-6 Not on form

Please provide a brief rational:

brfrat1_eevl

chnginfc_eevl

9. Should a change in the informed consent document(s) be considered to better inform and protect the rights and welfare of study subjects?

-9
1 Yes
0 No (specify)
-6 Not on form

Please provide a brief rational:

brfrat2_eevl

witness_eevl

10. Was the event witnessed on-site by study staff?

-9
1 Yes
0 No
-6 Not on form

11. Primary Organ System Code

orgsys_eevl

_____

Name - Please Print

_____ _____

Signature of Medical Safety Officer Date

submit