Serious Adverse Event (SAE) Initialization: Pre-Registration

Cycle _____ (*derived field*)

Do you have a serious adverse event (SAE) to report during pre-registration? *(check one)* ☐Yes ☐No

Comments

_____

_____

_____

Adverse Events

Form Instructions:
- This form contains both solicited and unsolicited AEs.
  - o Solicited AEs are those events expected per the protocol, defaulted on this form and denoted by a check mark in the Solicited column below.
  - o Unsolicited AEs can be added by clicking "Add a new Log line"

Cycle *(derived)* _____

Start date of <u>this cycle</u> *(derived only in the baseline folder) (dd MMM yyyy)* __ __ - __ __ __ - __ __ __ __

Reporting period end date *(dd MMM yyyy)* __ __ - __ __ __ - __ __ __ __

Start date of <u>first cycle</u> *(derived) (dd MMM yyyy)* __ __ - __ __ __ - __ __ __ __

Treatment assignment code *(derived)* _____

(If other), treatment assignment description *(derived)* _____

Verbatim term	Solicited *(derived)*	Adverse event term (CTCAE v4.0)	MedDRA adverse event code (CTCAE v4.0) *(derived)*	Adverse event evaluated this cycle?	Adverse event grade description (first 120 characters)	Adverse event (grade) grade description (full description) *(derived)*	Attribution to study intervention *(if grade >0)*	Did the adverse event result in any of the following? *(check all that apply)*
	☐			☐Yes ☐No ☐Pending	☐0 ☐1 ☐2 ☐3 ☐4 ☐5 (death)		☐Unrelated ☐Unlikely ☐Possible ☐Probable ☐Definite	☐None ☐Hospitalization ☐Life-threatening ☐Death ☐Disability ☐Congenital anomaly/birth defect ☐Required intervention ☐Other

(add a log line for each adverse event experienced)

INSTRUCTIONS: After entering new or modified data in the table above, adverse events must be submitted to caAERS for rules validation via the Expedited Reporting CRF in Rave.

Comments

_____

_____

Expedited Reporting Evaluation

Form Instructions:
- This form is used to send AEs recorded in the "Adverse Event Form" for rules validation in the caAERS system.
- Select the check box, "Send all AEs for rules validation" and save the form to determine if an AE requires expedited reporting.
- If at least one Adverse Event is identified to be serious for this cycle, a folder named "Expedited Reports" will be created containing forms required to submit the expedited report.
    - If the "Recommended report type by caAERS" is "CTEP 24 Hour SAE Notification", the "Report type to be submitted to caAERS (user selected)" must be "CTEP 24 Hour SAE Notification".
    - If the "Recommended report type by caAERS" is "CTEP 10 Calendar Day SAE Report", the "Report type to be submitted to caAERS (user selected)" can either be "CTEP 24 Hour SAE Notification" or "CTEP 10 Calendar Day SAE Report"; however, the selection chosen will change the expectancy of timeliness of the report.
    - If an expedited report has been started but not yet submitted and due to a modification of at least one Serious Adverse Event attribute, where the Adverse Event is no longer identified as serious, the user may choose to withdraw the expedited report by selecting the "Withdraw the expedited report" check box.
- Adverse Events listed on this form have been determined by caAERS as serious requiring expedited reporting.

NOTE: A delay is expected when the safety system is called for AE evaluation.

Error message from caAERS:

Cycle _____ (*derived field*)

Send all AEs for evaluation ☐

Recommended action for report type by caAERS *(derived) (check one)*
☐CREATE ☐UPDATE ☐AMEND ☐WITHDRAW ☐REPLACE ☐EDIT

Recommended report type by caAERS *(derived) (check one)*
☐CTEP 24 Hour SAE Notification
☐CTEP 5 Calendar Day SAE Report
☐CTEP 10 Calendar Day SAE Report
☐CTEP 15 Calendar Day SAE Report

Report type to be submitted to caAERS (user selected) (edit this field only if selecting to override the caAERS recommendation)
☐CTEP 24 Hour SAE Notification
☐CTEP 5 Calendar Day SAE Report
☐CTEP 10 Calendar Day SAE Report
☐CTEP 15 Calendar Day SAE Report

Report due by *(derived) (dd MMM yyyy)* __ __ - __ __ __ - __ __ __ __

Withdraw the expedited report ☐