

ADVERSE EVENT/INTERCURRENT ILLNESS FORM

Project Number	Period	Subj. No	Dose Time and Date
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List adverse events/illness each visit. If **“severity” changes**, record date/time of change as “resolution”, then begin new AE entry for new severity grade**. If an **AE continues over more than one visit**, continue to follow-up and document until “stable” ** or resolved.

AE#	Adverse Event /Illness	Solicited ?	Severity** 1=mild 2=mod 3=severe* **If change, record as new AE	Date and Time of Onset Mo Day Yr (Time) ___ am/pm	Date and Time of Resolution / Stability ++ Mo Day Yr (Time) ___ am/pm	Frequency 1=single 2=multiple 3=persistent	Therapeutic Measures Study Drug	Outcome	Temporal Relationship 1= Yes 2 = No 3= Insufficient evidence/ uncertain	Obvious Non Study Drug Cause	Reporter's Initials
		Y / N		__ __ __ _____ am/pm	__ __ __ _____ am/pm						
		Y / N		__ __ __ _____ am/pm	__ __ __ _____ am/pm						
		Y / N		__ __ __ _____ am/pm	__ __ __ _____ am/pm						
		Y / N		__ __ __ _____ am/pm	__ __ __ _____ am/pm						
		Y / N		__ __ __ _____ am/pm	__ __ __ _____ am/pm						

*Severe = life threatening or requiring emergency treatment, hospitalization or prescription drug. **Notify PI / Sponsor as occurrence of SAE.**

++Document if event is still ongoing at time of discharge. Continue to follow and document until AE has resolved or is stable. **Stability:** no significant change over ___ visits / weeks / months (circle one).

Therapeutic Measures- Study Drug

- 1-Withdrawn
- 2-Dosage Reduced
- 3-None
- 4-Uncertain
- 5-Therapeutic Failure
- 6-Temporary interruption of treatment
- 7-Other, clarify on comment sheet

Obvious Non-Study Drug Cause of AE

- 1-No
- 2-Yes, primary disease caused AE
- 3-Yes, other clinical condition caused AE
- 4-Yes, primary disease and other condition caused AE
- 5-Yes, causal relationship biologically implausible
- 6-Yes, AE associated with concomitant medication
- 7= Uncertain

Outcome

- 1-complete recovery
- 2-alive with sequelae
- 3-death
- 4-unknown/lost to follow-up
- 5-AE persisting, continue to follow
- 6- AE persisting but stable

*****It is acceptable to have more than 1 code when applicable.*****

