

## GRAIL 3 - NOTE TO FILE

### Adverse Event

SUBJECT ID: \_\_\_\_\_

SITE NUMBER: \_\_\_\_\_

Date AE reported to site	
Adverse event (AE)	
Onset date	
At which visit was this adverse event first reported?	<input type="checkbox"/> Visit 0 – Screening <input type="checkbox"/> Visit 1 – Day 1 – Enrollment <input type="checkbox"/> Visit 2 – Day 4 (+/-1) <input type="checkbox"/> Visit 3 – Day 7 (+/-1) <input type="checkbox"/> Visit 4 – Day 11 (+/-1) <input type="checkbox"/> Visit 5 – Day 14 (+/-1) <input type="checkbox"/> Visit 6 – Day 18 (+/-1) <input type="checkbox"/> Visit 7 – Day 21 (+/-1) <input type="checkbox"/> Visit 8 – Day 25 (+/-1) <input type="checkbox"/> Visit 9 – Day 28 (+/-1) <input type="checkbox"/> Visit 10 – Day 180 (+/- 42) <input type="checkbox"/> Interim Visit
If "Interim visit", specify interim visit code.	
Is the AE still ongoing?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "No", outcome date	
Severity grade	<input type="checkbox"/> Grade 1 (Mild) <input type="checkbox"/> Grade 2 (Moderate) <input type="checkbox"/> Grade 3 (Severe) <input type="checkbox"/> Grade 4 (Potentially life-threatening) <input type="checkbox"/> Grade 5 (Death)

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Relationship to study product <i>Record pertinent details for relationship assessment in "Comments".</i>	<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related
Action taken with study product	<input type="checkbox"/> Dose not changed <input type="checkbox"/> Dose reduced <input type="checkbox"/> Drug withdrawn <input type="checkbox"/> Drug interrupted <input type="checkbox"/> Not applicable
Other actions <i>Mark "None" or all that apply.</i>	<input type="checkbox"/> None <input type="checkbox"/> Medication(s) <input type="checkbox"/> Therapeutic procedure/surgery <input type="checkbox"/> Diagnostic procedure <input type="checkbox"/> Other
If "Other", specify	
Status/Outcome <i>If "Severity/Frequency increased" is selected, report as a new adverse event.</i>	<input type="checkbox"/> Recovered/Resolved; 2=Recovering/Resolving; <input type="checkbox"/> Recovered/Resolved with sequelae; <input type="checkbox"/> Not recovered/Not resolved; <input type="checkbox"/> Fatal <input type="checkbox"/> Severity/Frequency increased
If status or outcome is "Severity/Frequency increased", specify adverse event (include date)	
Is this a serious adverse event according to protocol guidelines? <i>If "No", go to "Has or will this AE be reported as an SAE?". If "Yes", check all that apply.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Results in death	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is life threatening	<input type="checkbox"/> Yes <input type="checkbox"/> No
Requires prolongation of existing hospitalization	<input type="checkbox"/> Yes <input type="checkbox"/> No

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Results in persistent or significant disability/incapacity	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has or will this AE be reported as a SAE? If "No", go to "Does this AE meet criteria for an Unanticipated Problem (UP)?"	<input type="checkbox"/> Yes <input type="checkbox"/> No
SAE onset date	
Does this AE meet criteria for an Unanticipated Problem (UP)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Was this AE a worsening of a baseline medical condition?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments	

**PRINT NAME:** \_\_\_\_\_

**SIGN NAME:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

**PI SIGNATURE AND DATE:** \_\_\_\_\_