Adverse Events

CDISC Clinical Data Connectathon

PROTOCOL NUMBER: 143-02 | VISIT ID: AE | CRF PAGE ID: AE

COMPOUND: SDP | THERAPEUTIC: ONC | COUNTRY: USA

SITE: ○ Fred Hutchinson Cancer Research Center ○ Memorial Sloan Kettering Cancer Institute ○ Roswell Park Cancer Institute

SCREENING / RANDOMIZATION #

Instructions: List one continuous Adverse Event per box and complete all fields when one of the following occurs: the severity increases, the event resolves or the patient terminates from the study.

01

Adverse Event Description

AE Start Date (mm/dd/yyyy) ___ / ___ / ____

SEVERITY: ○ Mild ○ Moderate ○ Severe ○ Life Threat

ACTION TAKEN REGARDING STUDY DRUG: ○ None ○ Discontinued Permanently ○ Reduced ○ Interrupted

AE Stop Date (mm/dd/yyyy) ___ / ___ / ____

RELATIONSHIP TO STUDY DRUG: ○ None ○ Unlikely ○ Possible ○ Probable

ACTIONS TAKEN REGARDING PATIENT CARE: ○ None ○ Medication required ○ Hospitalization required or prolonged ○ Other

ADVERSE EVENT OUTCOME: ○ Resolved, no residual effects ○ Continuing ○ Resolved, residual effects ○ Death

02

Adverse Event Description

AE Start Date (mm/dd/yyyy) ___ / ___ / ____

SEVERITY: ○ Mild ○ Moderate ○ Severe ○ Life Threat

ACTION TAKEN REGARDING STUDY DRUG: ○ None ○ Discontinued Permanently ○ Reduced ○ Interrupted

AE Stop Date (mm/dd/yyyy) ___ / ___ / ____

RELATIONSHIP TO STUDY DRUG: ○ None ○ Unlikely ○ Possible ○ Probable

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Comments:

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