

Listing 4: Intervention Group Events Potentially Related to the Study- Event Details (includes SAEs)

Study ID	Study Phase	Drug(s) Involved & Drug Action Preceding the Event ⁱ	Naranjo Score for Involved Drug(s)	Source of Medication Change	Description of Adverse Event	Can the event be attributed to intervention? Rationale

Listing 5: Protocol Violations

Treatment Group	Participant ID	Study Phase	Description of Violation	Actions Taken in Response to Protocol Violation

DO NOT REUSE