| **LSFAE03: Listing of Adverse Events Resulting in Death (Dummy Study: All Randomized Analysis Set)** | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Treatment Group/Country/Site ID | Subject ID | Age (years)/Sex/Race | Analysis Phase | Start Date/Study Start Day/Phase Start Day | End Date/Duration | Dictionary-Derived Term | Reported Term | Severity | Action Taken with Study Medication: Intranasal/Oral AD | Relationship to Study Medication (a): Intranasal/Oral AD | Outcome of Adverse Event/Duration (Days)/Serious Event | Dose at the time of Event |
| Dummy A/China/CN10023 | 60223061 | 52/Male/Asian | Double Blind | 23OCT2020/4/4 | -/- | Completed Suicide | Completed Suicide | Severe | Drug Withdrawn/Drug Withdrawn | Possible/Doubtful | Fatal/-/Y | 56 mg |
| (a) Relationship based on assessment of investigator. Note: \* indicates imputed AE start date or duration. Note: Adverse events resulting in DEATH are displayed. Note: Adverse events are coded using MedDRA version 23. | | | | | | | | | | | | |
| [LSFAE03.RTF] [Dummy compound\studyid\\DBR\_FINAL\RE\_CSR\PREPROD\LSFAE03.SAS] 20JAN2021, 02:30 | | | | | | | | | | | | |