SAE Supplemental Forms

SAE Supplemental Trigger

[Revision: Initial revision of study]

(Visit ID = 130 (*) / Visit Display Name = SAE Supplemental Forms / Visit Abbrev = SAE / PageID = 10 / Page Display Name = SAE Supplemental Trigger / Description = SAE Supplemental Trigger)

Enter the adverse event serial number(s) associated with this SAE case.

* Adverse event serial number	
Adverse event serial number	
Adverse event serial number	
Adverse event serial number	
Adverse event serial number	

SAE Supplemental form (check all that apply)

SAE Supplemental eCRF	☐
SAE Drug Information eCRF	☐

SAE Supplemental Details

[Revision: Initial revision of study]

(Visit ID = 130 (*) / Visit Display Name = SAE Supplemental Forms / Visit Abbrev = SAE / PageID = 20 / Page Display Name = SAE Supplemental Details / Description = SAE Supplemental Details)

* Adverse event serial number		
Adverse event serial number		
Adverse event serial number		
Adverse event serial number		
Adverse event serial number		
Date(s) of hospitalization		
Patient not hospitalized	☐	
* Admission date		(DD-MMM-YYYY)
* Discharge date		(UNK-UNK-UNK)
* Admission history and physical		
Admission history and physical continued		
* Any relevant laboratory results?	○ No ○ Yes	
* Please enter the relevant laboratory test result(s), unit(s), test date(s) and reference range(s).		
* Any relevant microbiology findings?	○ No ○ Yes	
* Please enter the relevant microbiology specimen date(s), test name(s), result(s) and finding(s).		

* Any relevant procedures?	○ No ○ Yes	
* Please enter the relevant procedure date(s), procedure name(s) and result description(s).		
* Weight at time of event (kg)		(format xxx.xx)
* Does the patient have risk factors relevant to event(s)	○ No ○ Yes	
* If yes, describe		
* Does the patient have family history relevant to event(s)	○ No ○ Yes	
* If yes, describe		
* Signs and symptoms associated with current serious adverse event(s)		
Signs and symptoms (cont.)		
* Has the patient experienced this/these event(s) before?	○ No ○ Yes	
* If yes, provide event(s) and prior date(s)		
* Clinical course of event		
Clinical course of event (cont.)		
Clinical course of event (cont.)		
Clinical course of event (cont.)		

SAE Drug Information

[Revision: Initial revision of study]

(Visit ID = 130 (*) / Visit Display Name = SAE Supplemental Forms / Visit Abbrev = SAE / PageID = 30 (*) / Page Display Name = SAE Drug Information / Description = SAE Drug Information)

Sequence number	
* Adverse event serial number	
Adverse event serial number	
Adverse event serial number	
Adverse event serial number	
Adverse event serial number	
* Drug name	
* Dose	

* Units

- kg
- g
- mg
- ug
- ng
- pg
- mg/kg
- ug/kg
- mg/m2
- ug/m2
- L
- mL
- Bq
- GBq
- MBq
- kBq
- Ci
- mCi
- uCi
- nCi
- mol
- mmol
- umol
- IU
- kIU
- MIU
- IU/kg
- mEq

	○ %
	○ DF
	○ gtt
	○ Other
* Other, specify	
* Route	○ Inhaled
	○ Intramuscular
	○ Intravenous
	○ Oral
	○ Rectal
	○ Subcutaneous
	○ Sublingual
	○ Topical
	○ Vaginal
	○ Intravascular
	○ Transmucosal
	○ Percutaneous (transdermal)
	○ Intradermal
	○ Cutaneous
	○ Other
* Other, specify	
* Frequency	○ One a day (QD)
	○ Twice a day (BID)
	○ Three times a day (TID)
	○ Four times a day (QID)
	○ As needed (PRN)
	○ Other

* Other, specify		
* Drug start date		(UNK-UNK-UNK)
* Has drug been interrupted due to this adverse event?	○ No ○ Yes	
* Date of last dose taken prior to drug interruption		(UNK-UNK-UNK)
* Was drug re-introduced?	○ No ○ Yes	
* Date re-introduced		(UNK-UNK-UNK)
* Did event reappear?	○ No ○ Yes	
* Indicate which event(s)		
* Has drug been permanently discontinued?	○ No ○ Yes	
* Date of last dose		(UNK-UNK-UNK)