

Form: Adverse Event

Adverse Event:	
(List diagnosis or each symptom separately)	AETERM \$
AE serious:	AESER \$ Yes
	No
Start Date: (DD MMM YYYY)	AESTDTC \$
Start Time: (00:00-23:59)	7.2375760
End Date: (DD MMM YYYY)	AEENDTC \$
End Time: (00:00-23:59)	
Check if Ongoing:	AEENRTPT \$ = [ONGOING] Ongoing
Related to Study Treatment:	AEREL \$ Related
	Not Related
Related to Study Procedures:	L \$ where QNAM \$ = [AERELPRC] Yes
	No
Action Taken with Study Treatment:	Dose Not Changed
	AEACN \$ Drug Interrupted
	Drug Withdrawn
	Not Applicable
	Unknown
Other Action Taken: (Check all that apply)	
None:	QVAL \$ where QNAM \$ = [AEACNOT4]
Medication Required: AECONTRT \$	QVAL \$ where QNAM \$ = [AEACNOT1]
Other Treatment Required:	QVAL \$ where QNAM \$ = [AEACNOT2]
Permanent <u>Study</u> Discontinuation:	QVAL \$ where QNAM \$ = [AEACNOT3]
AE Toxicity Grade:	GRADE 1
	AETOXGR \$ GRADE 2
	GRADE 3
	GRADE 4
Seriousness Criteria (Check all that apply for thi event)	s <u>AESDTH</u> \$
Death:	
Life Threatening:	AESLIFE \$
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Form: Adverse Event

	Yes
Did the AE result in Initial or Prolonged Hospitalization for the subject?	AESHOSP \$ Yes
Persistent or significant disability/incapacity:	AESDISAB \$ Yes
Congenital anomaly / birth defect:	AESCONG \$ Yes
Other significant medical event:	AESMIE \$ Yes

Note: To add additional adverse events, please complete an additional form, by clicking on 'Add a new log line'.

If Adverse Event is Serious, please refer to the regulatory binder for an SAE Report form. Complete an SAE Report and fax the SAE Report within 24 hours of the Reporter's knowledge of the event.

Contact information for faxing these forms:

If the Adverse Event is Serious, please click the [?] help text to open the SAE Report Form. Please fill in the form and fax to the contact information provided.

A Serious Adverse Event is any adverse experience that results in any of the following outcomes:

- (1) Death,
- (2) Is life-threatening (at immediate risk of death at time of the event),
- (3) Requires subject hospitalization or prolonged hospitalization,
- (4) Persistent or significant disability/incapacity,
- (5) Congenital abnormality/birth defect or
- (6) Any other important Medical Event based on clinician's judgment or may require medical or surgical intervention to prevent one of the other serious criteria.

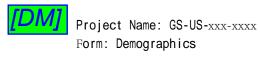
Refer to protocol for protocol-specific SAE definitions.

Project Name: GS-US-xxx-xxxx Form: Adverse Event Summary

Did the subject experience any Adverse Events during the protocol defined collection period?

Not Submitted

Not Submitted



Sex at birth: SEX S	Date of Birth: (DD MMM YYYY)	BRTHDTC \$
Ethnicity: Hispanic of Latino Not Permitted Race: American Indian or Alaska Native Asian Black Black Native Hawaiian or Pacific Islander White Not Permitted Other	Sex at birth:	SEX \$ Male
Race: American Indian or Alaska Native Asian Black RACES Native Hawaiian or Pacific Islander White Not Permitted Other		Female
Race: American Indian or Alaska Native Asian Black RACES Native Hawaiian or Pacific Islander White Not Permitted Other	Ethnicity:	Hispanic & Latino
Race: American Indian or Alaska Native Asian Black RACES Native Hawaiian or Pacific Islander White Not Permitted Other		ETHNIC \$ Not Hispanic of Latino
Native Asian Black RACES Native Hawaiian or Pacific Islander White Not Permitted Other		Not Permitted
	Race:	Native Asian Black Native Hawaiian or Pacific Islander White Not Permitted
	If Race is Other, please specify:	

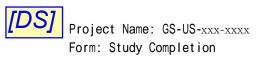


DSCAT \$ = [PROTOCOL MILESTONE] DSSCAT \$ = [ENROLLMENT]

Project Name: GS-US-xxx-xxxx

Form: Enrollment

Note: All Day 1 tests and procedures, including ECGs, enrollment and dosing/dispensing of study drug.	, must be completed prior to	
Was the Subject Enrolled?	DSTERM \$ = [ENROLLED] Yes No Not S	Submitted
Complete the Inclusion/Exclusion Criteria form to corcriterion.	nfirm the result for each	
If Enrolled, Date of Enrollment: (DD MMM YYYY)	DSSTDTC \$	
4-Digit Subject Number:	Not Submitted	
Cohort Assignment: QVAL \$ where QN	Cohort 1 Cohort 2 Cohort 3 Cohort 4 Cohort 5 Cohort 6 Cohort 7	
If subject did not meet inclusion/exclusion criteria was enrolled, please provide an explanation:	and DSTERM \$	
DSDECOD \$ = [ENROLLED DESPITE INCLU- NOT MET/EXCLUSION CRITERIA MET]	USION CRITERIA	



DSCAT \$ = [DISPOSITION EVENT] DSSCAT \$ = [STUDY COMPLETION]

Did the subject complete the protocol-pl	anned duration DSTERM \$ = [COMPLETED] Yes
of the study?	No Not Submitted
If "No", please specify reason for study	Adverse Event
discontinuation:	DSTERM \$ Death
	Pregnancy
	Investigator's Discretion
	Protocol Violation
	Withdrew Consent
	Lost to Follow-Up
	Study Terminated by Sponsor



Form: Study Drug Administration (PK)

		=
Timepoint:	VISIT \$ Day 1	
	Day 8	
	Day 9	$\vec{)}$
	Day 10	$\vec{)}$
	Day 11	$\vec{)}$
	Day 12	5
	Day 13	$\bar{)}$
	Day 14	Ō
Drug Name:	EXTRT \$ GS-5801/PTM	$\overline{)}$
	GS-5801	J
Was study drug taken?	Not Submitted Yes	$\overline{)}$
	No	J
Dose per administration:	EXDOSE #	

 $\label{eq:project_Name: GS-US-xxx-xxxx} \text{Project Name: GS-US-} \\ \text{xxx-xxxx}$

Form: Study Drug Administration (PK)

Dose Units:	EXDOSU \$	kg
		g
		mg
		ug
		ng
		pg
		mg/kg
		ug/kg
		mg/m2
		ug/m2
		liter 🔵
		m I 🔘
		ul 🔘
		Bq
		GBq
		MBq
		Kbq
		mo I
		mmo I
		umo I
		ΙU
		kIU 🔵
		mIU
		IU/kg
		mEq
		%
		gtt
		Other
Dosing Frequency:	EXDOSFRQ \$	
		0nce O
Route:	EXROUTE	💲 Oral 🦱
Dose Date: (DD MMM YYYY)		EXSTDTC \$
Dose Time: (00:00-23:59)		\leftarrow

Form: Study Drug Administration (PK)

Was the subject fasting?	QVAL \$ where QNAM \$ = [EXFASTYN] Yes No
If No, please specify:	
Date of last meal prior to dose: (DD MMM	,
Time of last meal prior to dose: (00:00- Was dose taken with food?	QVAL \$ where QNAM \$ = [EXFOODYN] Ves No
Was 100% of predose meal completed?	QVAL \$ where QNAM \$ = [EXPRMEAL] Yes No
Start time of predose meal: (00:00-23:59	,
End time of predose meal: (00:00-23:59)	QVAL \$ where QNAM \$ = [EXMENTIM]



Project Name: GS-US-xxx-xxxx Form: Study Drug Completion

DSCAT \$ = [DISPOSITION EVENT]

DSSCAT \$ = [STUDY DRUG COMPLETION]

Study Phase Completion:	Not Submitted Treatment	
	Blinded Treatment	
Did subject complete study drug dosing as specif	ied per DSTERM \$ = [COMPLETED] Yes	
protocol?	No No Not	Submitted
If "No", please specify reason for study <u>drug</u>	DSTERM \$ Adverse Event	
discontinuation:	Death	
	Pregnancy	
	Investigator's Discretion*	
	Subject Never Dosed with Study Drug	
Protocol Violation		
	Subject Decision*	
	Study Terminated by Sponsor	
*For discontinuation reasons of Subject Decision Investigator's Discretion and Lost to Follow-up, provide additional details:		

[DM] [MH]	Project Name: GS-US-xxx-xxxx Form: Visit Date			
[IE] [VS]	Was the visit performed? Visit Date: (DD MMM YYYY) DMDTC \$ MHDTC \$ IEDTC \$	VSDTC \$		es(No(
[SC] [RP]	Please check all forms for each assessment performed at this unscheduled visit:	_		
	Vital Signs:	Not Submi	itted	

ECG:

Not Submitted