Blank CRF's

[AE]

Project Name: GS-US-xxx-xxxx
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)

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: QVAL $ where QNAM $ = [AERELPRC] Yes ☐ No ☐

Action Taken with Study Treatment: AEACN $

Dose Not Changed ☐
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Drug Withdrawn ☐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 Study Discontinuation: QVAL $ where QNAM $ = [AEACNOT3]

AE Toxicity Grade: AETOXGR $

GRADE 1 ☐
GRADE 2 ☐
GRADE 3 ☐
GRADE 4 ☐

Seriousness Criteria *(Check all that apply for this event)* AESDTH $ Yes ☐

Death:

Life Threatening: AESLIFE $

[AE]

Project Name: GS-US-xxx-xxxx
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.

Did the subject experience any Adverse Events during the protocol defined collection period?	Not Submitted	Yes ☐ No ☐

[DM]

Project Name: GS-US-xxx-xxxx

Form: Demographics

Date of Birth: (DD MMM YYYY)	BRTHDTC $	
Sex at birth:	SEX $	Male ☐ Female ☐
Ethnicity:	ETHNIC $	Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not Permitted ☐
Race:	RACE $	American Indian or Alaska Native ☐ Asian ☐ Black ☐ Native Hawaiian or Pacific Islander ☐ White ☐ Not Permitted ☐ Other ☐
If Race is Other, please specify:	QVAL $ where QNAM $ = [RACEOTH]	

[DS]
[DM]

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

Project Name: GS-US-xxx-xxxx
Form: Enrollment

Note: All Day 1 tests and procedures, including ECGs, must be completed prior to enrollment and dosing/dispensing of study drug.

Was the Subject Enrolled? DSTERM $ = [ENROLLED] Yes ☐ No ☐ Not Submitted

Complete the Inclusion/Exclusion Criteria form to confirm the result for each criterion.

If Enrolled, Date of Enrollment: (DD MMM YYYY) DSSTDTC $

4-Digit Subject Number: Not Submitted

Cohort Assignment: QVAL $ where QNAM $ = [COHORT]

- ☐ Cohort 1
- ☐ Cohort 2
- ☐ Cohort 3
- ☐ Cohort 4
- ☐ Cohort 5
- ☐ Cohort 6
- ☐ Cohort 7

If subject did not meet inclusion/exclusion criteria and was enrolled, please provide an explanation: DSTERM $

DSDECOD $ = [ENROLLED DESPITE INCLUSION CRITERIA NOT MET/EXCLUSION CRITERIA MET]

[DS]

Project Name: GS-US-xxx-xxxx

Form: Study Completion

DSCAT $ = [DISPOSITION EVENT]

DSSCAT $ = [STUDY COMPLETION]

Did the subject complete the protocol-planned duration of the study? DSTERM $ = [COMPLETED]

- Yes ☐
- No ☐ Not Submitted

If "No", please specify reason for study discontinuation: DSTERM $

- Adverse Event ☐
- Death ☐
- Pregnancy ☐
- Investigator's Discretion ☐
- Protocol Violation ☐
- Withdrew Consent ☐
- Lost to Follow-Up ☐
- Study Terminated by Sponsor ☐

[EX]

Project Name: GS-US-xxx-xxxx
Form: Study Drug Administration (PK)

Timepoint:	VISIT $	Day 1 ☐
		Day 8 ☐
		Day 9 ☐
		Day 10 ☐
		Day 11 ☐
		Day 12 ☐
		Day 13 ☐
		Day 14 ☐
Drug Name:	EXTRT $	GS-5801/PTM ☐
		GS-5801 ☐
Was study drug taken?	Not Submitted	Yes ☐
		No ☐
Dose per administration: _____	EXDOSE #	

Project Name: GS-US-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 ☐ ml ☐ ul ☐ Bq ☐ GBq ☐ MBq ☐ Kbq ☐ mol ☐ mmol ☐ umol ☐ IU ☐ kIU ☐ mIU ☐ IU/kg ☐ mEq ☐ % ☐ gtt ☐ Other ☐
Dosing Frequency:	EXDOSFRQ $	Daily ☐ Once ☐
Route:	EXROUTE $	Oral ■
Dose Date: (DD MMM YYYY)	EXSTDTC $	
Dose Time: (00:00-23:59)		

Project Name: GS-US-xxx-xxxx
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 YYYY)	QVAL $ where QNAM $ = [EXMEADAT]	
Time of last meal prior to dose: (00:00-23:59)	QVAL $ where QNAM $ = [EXMEATIM]	
Was dose taken with food?	QVAL $ where QNAM $ = [EXFOODYN]	Yes ☐ No ☐
Was 100% of predose meal completed?	QVAL $ where QNAM $ = [EXPRMEAL]	Yes ☐ No ☐
Start time of predose meal: (00:00-23:59)	QVAL $ where QNAM $ = [EXMSTTIM]	
End time of predose meal: (00:00-23:59)	QVAL $ where QNAM $ = [EXMENTIM]	

[DS]

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 specified per protocol? DSTERM $ = [COMPLETED]

- ☐ Yes
- ☐ No

Not Submitted

If "No", please specify reason for study drug discontinuation: DSTERM $

- ☐ Adverse Event
- ☐ Death
- ☐ Pregnancy
- ☐ Investigator's Discretion*
- ☐ Subject Never Dosed with Study Drug
- ☐ Protocol Violation
- ☐ Subject Decision*
- ☐ Study Terminated by Sponsor

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*For discontinuation reasons of Subject Decision, Investigator's Discretion and Lost to Follow-up, please provide additional details: QVAL $ where QNAM $ = [DSREASDC]

[DM]
[MH]
[IE]
[VS]
[SC]
[RP]

Project Name: GS-US-xxx-xxxx
Form: Visit Date

Was the visit performed? Not Submitted Yes ☐ No ☐

Visit Date: (DD MMM YYYY) DMDTC $ MHDTC $ IEDTC $ VSDTC $ SCDTC $ RPDTC $

Please check all forms for each assessment performed at this unscheduled visit:

Vital Signs: Not Submitted

ECG: Not Submitted