Study

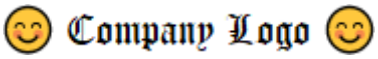
CRF Specification for Test Trial

Selection of CRF forms available at CDISC

Protocol Name:

Creation date: 2022-07-07 time: 10:54:53

My Company



Visit Matrix

Event/ Form	Screening	Visit 1	Death
Subject eligibility	✔		
Demographics	✔		
Background Heart Failure Maintenance Medications Part 1	✔		
Background Heart Failure Maintenance Medications Part 2	✔		
Prior Psoriasis Treatments	✔		
Body Sites of Psoriasis Involvement at Baseline	✔		
Adverse Events		✔	✔
ECG Test Results		✔	
Death			✔

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Subject eligibility

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Does the subject meet all inclusion criteria and none of the exclusion criteria?	○ Yes *(Y)* ○ No *(N)*	SUPPIE.QVAL, SUPPDM.QNAM=IEYN, SUPPDM.QLABEL='All inclusion/exclusion criteria met'
2.1	Seq. no.	*Integer*	IE.IESPID
2.2	Inclusion criteria not met *Tick all that apply*	☐ Inclusion 1 *(INCL01)* ☐ Inclusion 2 *(INCL02)* ☐ Inclusion 3 *(INCL03)* ☐ Inclusion 4 *(INCL04)* ☐ Inclusion 5 *(INCL05)* ☐ Inclusion 6 *(INCL06)* ☐ Inclusion 7 *(INCL07)* ☐ Inclusion 8 *(INCL08)* ☐ Inclusion 9 *(INCL09)* ☐ Inclusion 10 *(INCL10)*	IE.IETESTCD, IE.IETEST=TI.IETEST, IE.IECAT=TI.IECAT. If failed inclusion criteria, IE.IEORRES=N, IE.IESTRESC=N. If failed exclusion criteria, IE.IEORRES=Y, IE.IESTRESC=Y
3.1	Seq. no.	*Integer*	IE.IESPID
3.2	Exclusion criteria met *Tick all that apply*	☐ Exclusion 1 *(EXCL01)* ☐ Exclusion 2 *(EXCL02)* ☐ Exclusion 3 *(EXCL03)* ☐ Exclusion 4 *(EXCL04)* ☐ Exclusion 5 *(EXCL05)* ☐ Exclusion 6 *(EXCL06)* ☐ Exclusion 7 *(EXCL07)* ☐ Exclusion 8 *(EXCL08)* ☐ Exclusion 9 *(EXCL09)* ☐ Exclusion 10 *(EXCL10)*	IE.IETESTCD, IE.IETEST= TI.IETEST, IE.IECAT=TI.IECAT. If failed inclusion criteria, IE.IEORRES=N, IE.IESTRESC=N. If failed exclusion criteria, IE.IEORRES=Y, IE.IESTRESC=Y

Demographics

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Birth Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	DM.BRTHDTC, Partial dates are to be recorded according to ISO 8601
1.2	Sex	○ Female *(F)* ○ Male *(M)* ○ U; UNK; Unknown *(U)* ○ UNDIFFERENTIATED *(UNDIFFERENTIATED)*	DM.SEX
1.3	Ethnicity	○ HISPANIC OR LATINO *(HISPANIC OR LATINO)* ○ NOT HISPANIC OR LATINO *(NOT HISPANIC OR LATINO)* ○ Not reported *(NOT REPORTED)* ○ U; UNK; Unknown *(UNKNOWN)*	DM.ETHNIC
1.4	Race	○ AMERICAN INDIAN OR ALASKA NATIVE ○ ASIAN ○ BLACK OR AFRICAN AMERICAN ○ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER ○ NOT REPORTED ○ UNKNOWN ○ WHITE	DM.RACE

Background Heart Failure Maintenance Medications Part 1

Indicate whether the listed class/type of background heart failure medication was prescribed to the subject (see the study protocol for details)

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Were any angiotensin-converting enzyme (ACE) inhibitors taken?	○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CM.CMCAT='Heart Failure Maintenance Medication', CM.CMPRESP='Y', CM.CMTRT='ARBs'
1.2	If No, provide reason for not prescribing ARBs	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARBs'
1.3	Were any angiotensin receptor/neprilysin inhibitors (ARNIs) taken?	○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs'
1.4	If No, provide reason for not prescribing ARNIs	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)* ○ Cost 2 *(COST2)* ○ Unknown 2 *(UNKNOWN2)*	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs'
1.5	Were any aldosterone antagonists taken?	○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Aldosterone Antagonists'
1.6	If No, provide reason for not prescribing aldosterone antagonists	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Aldosterone Antagonists'
1.7	Was any hydralazine taken?	○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Hydralazine'

Background Heart Failure Maintenance Medications Part 1

Indicate whether the listed class/type of background heart failure medication was prescribed to the subject (see the study protocol for details)

Ref	CRF Question	Data Collected	SDTM Annotations
1.8	If No, provide reason for not prescribing hydralazine	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Hydralazine'
1.9	Were any diuretics taken?	○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Diuretics'
1.10	If No, provide reason for not prescribing diuretics	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Diuretics'

Background Heart Failure Maintenance Medications Part 2

List the specific background heart failure medications used. Include all heart failure medications that are to be continued. When a subject has frequent changes in the dose and schedule for oral diuretics, the dosing information can be recorded as PRN

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	What was the medication name?	*Text*	CM.CMTRT
1.2	What was the individual dose of the medication per administration?	*Integer*	CM.CMDOSE
1.3	What is the unit of the medication per administration?	○ mcg *(ug)* ○ mg *(mg)* ○ g *(g)* ○ Ml *(mL)* ○ Application *(APPLICATION)* ○ International Unit (IU) *(IU)* ○ Tablet *(TABLET)* ○ Capsule *(CAPSULE)* ○ Other *(OTHER)*	CM.CMDOSU, CM.CMCAT='ANTIPSORIATIC'
1.4	What was the frequency of the medication?	○ BD; Twice per day *(BID)* ○ As needed *(PRN)*	CM.CMDOSFRQ
1.5	What was the route of administration of the medication?	○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL	CM.CMROUTE, CM.CMCAT='ANTIPSORIATIC'
1.6	Start Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMSTDTC
1.7	Is the medication ongoing?	○ AFTER ○ BEFORE ○ COINCIDENT ○ DURING ○ DURING/AFTER ○ ONGOING ○ UNKNOWN	CM.CMENRTPT
1.8	End Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMENDTC, CM.CMCAT='ANTIPSORIATIC'
2.1	If applicable, was the medication given at the recommended regimen?	○ No *(N)* ○ Yes *(Y)*	SUPPCM.QVAL, SUPPCM.QNAM='CMRRGYN', SUPPCM.QLABEL='Was medication given at recom. regimen'

Background Heart Failure Maintenance Medications Part 2

List the specific background heart failure medications used. Include all heart failure medications that are to be continued. When a subject has frequent changes in the dose and schedule for oral diuretics, the dosing information can be recorded as PRN

Ref	CRF Question	Data Collected	SDTM Annotations
2.2	If applicable, why was the medication not given at the recommended regimen?	*Text*	SUPPCM.QVAL, SUPPCM.QVAL='CMRRGREA', SUPPCM.QLABEL='Why the medication not given at regimen'

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Has the subject had any psoriasis treatments before the study start?	○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMCAT='ANTIPSORIATIC', CMTRT='ANTIPSORIATIC', CMPRESP='Y', CMSTRF='BEFORE'
1.2	What is the subcategory for the treatment?	○ Biologic *(BIOLOGIC)* ○ Non-Biologic *(NON-BIOLOGIC)* ○ Phototherapy *(PHOTOTHERAPY)*	CM.CMSCAT, CMCAT='ANTIPSORIATIC'
1.3	What was the name of the treatment?	*Text*	CM.CMTRT, CMCAT='ANTIPSORIATIC'
1.4	What was the route of administration of the medication?	○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL	CM.CMROUTE, CM.CMCAT='ANTIPSORIATIC'
1.5	If the treatment was systemic, what was the individual dose?	*Text*	CM.CMDOSTXT, CMCAT='ANTIPSORIATIC', CMDOSE if all values of CMDOSTXT are numeric
1.6	What is the unit of the medication per administration?	○ mcg *(ug)* ○ mg *(mg)* ○ g *(g)* ○ Ml *(mL)* ○ Application *(APPLICATION)* ○ International Unit (IU) *(IU)* ○ Tablet *(TABLET)* ○ Capsule *(CAPSULE)* ○ Other *(OTHER)*	CM.CMDOSU, CM.CMCAT='ANTIPSORIATIC'
2.1	If the medication was a biologic, what device was used for drug administration?	○ Single-dose pen *(SINGLE-DOSE PEN)* ○ Multiple-dose pen *(MULTIPLE-DOSE PEN)* ○ Pre-filled syringe *(PRE-FILLED SYRINGE)* ○ Syringe *(SYRINGE)* ○ Not Applicable *(NOT APPLICABLE)*	SUPPCM.QVAL, SUPPCM.QNAM='SPDEVID', SUPPCM.QLABEL='Device Identifier'
3.1	Start Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMSTDTC, CMCAT='ANTIPSORIATIC'
3.2	Is the medication ongoing?	○ No *(N)* ○ Yes *(Y)*	CM.CMENRTPT, CMCAT='ANTIPSORIATIC', If Yes, CMENRTPT='ONGOING'. If No, CMENRF=blank

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected	SDTM Annotations
3.3	End Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMENDTC, CM.CMCAT='ANTIPSORIATIC'
4.1	What was the reason for treatment discontinuation?	○ Inadequate efficiacy *(INADEQUATE EFFICACY)* ○ Adverse event *(ADVERSE EVENT)* ○ Other-not related to efficacy/adverse event *(OTHER-NOT RELATED TO EFFICACY/ADVERSE EVENTS)*	SUPPCM.QVAL, SUPPCM.QNAM='CMRSDISC', SUPPCM.QLABEL='Reason for treatment discontinuation'

Body Sites of Psoriasis Involvement at Baseline

CRF Instructions: Use one page per affected area

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	What was the location of psoriasis lesion involvement?	○ FACE *(FACE)* ○ GENITALIA *(GENITALIA)* ○ Hand *(HAND)* ○ HEAD *(HEAD)* ○ Lower Extremity *(LIMB, LOWER)* ○ Upper Extremity *(LIMB, UPPER)* ○ SCALP *(SCALP)* ○ Torso *(TRUNK)*	QS.QSLOC, QSTESTCD='LESIDENT',QSTEST='Lesion Identification'
1.2	If applicable, what was the laterality of the anatomical location?	○ LEFT ○ RIGHT ○ NOT APPLICABLE	QS.QSLAT, QSTESTCD='LESIDENT', QSTEST='Lesion Identification'
1.3	If applicable, what was the directionality of the anatomical location?	○ ANTERIOR ○ POSTERIOR ○ NOT APPLICABLE	QS.QSDIR, QSTESTCD='LESIDENT', QSTEST='Lesion Identification'

Adverse Events

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Were any adverse events experienced?	○ No *(N)* ○ Yes *(Y)*	NOT SUBMITTED
1.2	AE Group ID	*Text*	AE.AEGRPID
1.3	What is the adverse event term?	*Text*	AE.AETERM
2.1	AE Identifier	*Integer*	AE.AESPID
2.2	What is the date the adverse event started?	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	AE.AESTDTC, Partial dates are stored according to ISO8601
2.3	Is the adverse event still ongoing?	*Text*	AE.AEENTPT, If Yes, AE.AEENTPT=ONGOING. If No, AE.AEENTPT=BEFORE
2.4	End date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	AE.AEENDTC, Partial dates are stored according to ISO8601
2.5	What is the toxicity grade of the adverse event?	○ Absent *(0)* ○ Mild *(1)* ○ Moderate *(2)* ○ Severe *(3)* ○ Life Threatening *(4)* ○ Fatal *(5)*	AE.AETOXGR
2.6	Is the adverse event serious?	○ No *(N)* ○ Yes *(Y)*	AE.AESER
2.7	Congenital Anomaly or Birth Defect	☐ No *(N)* ☐ Yes *(Y)*	AE.AESCONG
2.8	Significant Disability	☐ No *(N)* ☐ Yes *(Y)*	AE.AESDISAB
2.9	Death	☐ No *(N)* ☐ Yes *(Y)*	AE.AESDTH
2.10	Hospitalization	☐ No *(N)* ☐ Yes *(Y)*	AE.AESHOSP
2.11	Life Threatening	☐ No *(N)* ☐ Yes *(Y)*	AE.AESLIFE
2.12	Occurs with Overdose	☐ No *(N)* ☐ Yes *(Y)*	AE.AESOD
2.13	Other Medically Important Event	☐ No *(N)* ☐ Yes *(Y)*	AE.AESMIE
2.14	Concomitant or Additional Treament Given	☐ No *(N)* ☐ Yes *(Y)*	AE.AECONTRT

Adverse Events

Ref	CRF Question	Data Collected	SDTM Annotations
2.15	Is this event related to study treatment?	○ No *(N)* ○ Yes *(Y)*	AE.AEREL
2.16	Relationship to Non-Study Treatment	○ Adjunct Therapy *(ADJUNCT THERAPY)* ○ Concomitant Therapy *(CONCOMITANT THERAPY)* ○ Study Device *(STUDY DEVICE)* ○ Study Disease *(STUDY DISEASE)* ○ Study Procedure *(STUDY PROCEDURE)* ○ Other Medical Condition *(OTHER MEDICAL CONDITION)*	AE.AERELNST
2.17	What was the outcome of this adverse event?	○ Fatal *(FATAL)* ○ Not recovered/not resolved *(NOT RECOVERED/NOT RESOLVED)* ○ Recovered/resolved with sequelae *(RECOVERED/RESOLVED WITH SEQUELAE)* ○ Recovered/resolved *(RECOVERED/RESOLVED)* ○ Recovering/resolving *(RECOVERING/RESOLVING)* ○ Unkmown *(C49496)*	AE.AEOUT
2.18	What action was taken with study treatment?	○ Dose not changed *(DOSE NOT CHANGED)* ○ Dose reduced *(DOSE REDUCED)* ○ Dose increased *(DOSE INCREASED)* ○ Drug interrupted *(DRUG INTERRUPTED)* ○ Drug withdrawn *(DRUG WITHDRAWN)* ○ Not applicable *(NOT APPLICABLE)* ○ Unknown *(UNKNOWN)*	AE.AEACN
3.1	Is this event a dose limiting toxicity?	○ No *(N)* ○ Yes *(Y)*	SUPPAE.QVAL, SUPPAE.QNAM=AEDLTOXF, SUPPAE.QLABEL='Dose Limiting Toxicity'

ECG Test Results

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Was the ECG performed?	○ No *(N)* ○ Yes *(Y)*	NOT SUBMITTED
2.1	What was the ECG date?	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	EG.EGSTDTC, Date and time are to be combined into one variable according to ISO 8601
2.2	What was the ECG time?	HH:MM *Time* *Always collect times as HH:MM and store times as ISO8601 in SDTM.*	EG.EGSTDTC, Date and time are to be combined into one variable according to ISO 8601
2.3	What was the result of the ECG?	○ Normal *(NORMAL)* ○ Abnormal *(ABNORMAL)*	EG.EGORRES
3.1	Was the ECG clinically significant?	○ No *(N)* ○ Yes *(Y)*	SUPPEG.QVAL, SUPPEG.QNAM='EGCLSIG', SUPPEG.QLABEL='ECG clinically significant'

Death

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Were any death detail assessments collected?	○ No *(N)* ○ Yes *(Y)*	NOT SUBMITTED
2.1	Collection Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	DD.DDDTC
3.1	Death Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	DD.DTHDTC
4.1	What is the primary cause of death?	*Text*	DD.DDORRES, DD.DDTESTCD='DIAGPRIM', DD.DDTEST='Primary Diagnosis'
4.2	What is the secondary cause of death?	*Text*	DD.DDORRES, DD.DDTESTCD='DIAGSEC', DD.DDTEST='Secondary Diagnosis'
4.3	What is the location of death?	○ Home *(HOME)* ○ Hospital *(HOSPITAL)* ○ Nursing/Rehabilitation Home *(NURSING/REHABILITATION HOME)*	DD.DDORRES, DD.DDTESTCD='LOCDTH', DD.DDTEST='What is the location of death'
4.4	Was the death witnessed?	*Text*	DD.DDORRES, DD.DDTESTCD='DTHWIT', DD.DDTEST='Was Death Witnessed'