Study

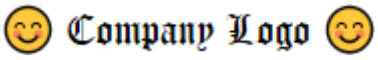
CRF Specification for Test Trial

Selection of CRF forms available at CDISC

Protocol Name:

Creation date: 2022-04-08T15:54:16+02:00

Your Company



Visit Matrix

Event/ Form	Screening Visit 1	Death
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		✔

Demographics

Ref	CRF Question	Data Collected	SDTM Annotations
1.1		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	DM.BRTHDTC,
1.2		○ Female *(F)* ○ Male *(M)* ○ U; UNK; Unknown *(U)* ○ UNDIFFERENTIATED *(UNDIFFERENTIATED)*	DM.SEX
1.3		○ 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		○ 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		○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMPRESP='Y', CMTRT='ARBs'
1.2		○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, CMPRESP='Y', CMTRT='ARBs'
1.3		○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMPRESP='Y', CMTRT='ARNIs'
1.4		○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)* ○ Cost 2 *(COST2)* ○ Unknown 2 *(UNKNOWN2)*	CM.CMREASND, CMPRESP='Y', CMTRT='ARNIs'
1.5		○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMPRESP='Y', CMTRT='Aldosterone Antagonists'
1.6		○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, CMPRESP='Y', CMTRT='Aldosterone Antagonists'
1.7		○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMPRESP='Y', CMTRT='Hydralazine'

Background Heart Failure Maintenance Medications Part 1

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Ref	CRF Question	Data Collected	SDTM Annotations
1.8		○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, CMPRESP='Y', CMTRT='Hydralazine'
1.9		○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMPRESP='Y', CMTRT='Diuretics'
1.10		○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*	CM.CMREASND, 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		*Text*	CM.CMTRT
1.2		*Integer*	CM.CMDOSE
1.3		○ mcg *(ug)* ○ mg *(mg)* ○ g *(g)* ○ Ml *(mL)* ○ Application *(APPLICATION)* ○ International Unit (IU) *(IU)* ○ Tablet *(TABLET)* ○ Capsule *(CAPSULE)* ○ Other *(OTHER)*	CM.CMDOSU,
1.4		○ BD; Twice per day *(BID)* ○ As needed *(PRN)*	CM.CMDOSFRQ
1.5		○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL	CM.CMROUTE,
1.6		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMSTDTC
1.7		○ AFTER ○ BEFORE ○ COINCIDENT ○ DURING ○ DURING/AFTER ○ ONGOING ○ UNKNOWN	CM.CMENRTPT
1.8		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMENDTC,

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
2.1		○ No *(N)* ○ Yes *(Y)*	SUPPCM.QVAL, SUPPCM.QLABEL='Was medication given at recom. regimen'
2.2		*Text*	SUPPCM.QVAL, SUPPCM.QLABEL='Why the medication not given at regimen'

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected	SDTM Annotations
1.1		○ No *(N)* ○ Yes *(Y)*	CM.CMOCCUR, CMTRT='ANTIPSORIATIC', CMPRESP='Y', CMSTRF='BEFORE'
1.2		○ Biologic *(BIOLOGIC)* ○ Non-Biologic *(NON-BIOLOGIC)* ○ Phototherapy *(PHOTOTHERAPY)*	CM.CMSCAT,
1.3		[ ] *Text*	CM.CMTRT,
1.4		○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL	CM.CMROUTE,
1.5		[ ] *Text*	CM.CMDOSTXT, CMDOSE if all values of CMDOSTXT are numeric
1.6		○ mcg *(ug)* ○ mg *(mg)* ○ g *(g)* ○ Ml *(mL)* ○ Application *(APPLICATION)* ○ International Unit (IU) *(IU)* ○ Tablet *(TABLET)* ○ Capsule *(CAPSULE)* ○ Other *(OTHER)*	CM.CMDOSU,
2.1		○ 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.QLABEL='Device Identifier'
3.1		[DD-MMM-YYYY] *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMSTDTC,

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected	SDTM Annotations
3.2		○ No *(N)* ○ Yes *(Y)*	CM.CMENRTPT, If Yes, CMENRTPT='ONGOING'. If No, CMENRF=blank
3.3		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	CM.CMENDTC,
4.1		○ 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.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		○ FACE *(FACE)* ○ GENITALIA *(GENITALIA)* ○ Hand *(HAND)* ○ HEAD *(HEAD)* ○ Lower Extremity *(LIMB, LOWER)* ○ Upper Extremity *(LIMB, UPPER)* ○ SCALP *(SCALP)* ○ Torso *(TRUNK)*	QS.QSLOC, QSTEST='Lesion Identification'
1.2		○ LEFT ○ RIGHT ○ NOT APPLICABLE	QS.QSLAT, QSTEST='Lesion Identification'
1.3		○ ANTERIOR ○ POSTERIOR ○ NOT APPLICABLE	QS.QSDIR, QSTEST='Lesion Identification'

Adverse Events

Ref	CRF Question	Data Collected	SDTM Annotations
1.1		○ No *(N)* ○ Yes *(Y)*	AE.NOT,
1.2		*Text*	AE.AEGRPID
1.3		*Text*	AE.AETERM
2.1		*Integer*	AE.AESPID
2.2		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	AE.AESTDTC,
2.3		*Text*	AE.AEENTPT, AEENTPT=ONGOING. If No, AEENTPT=BEFORE
2.4		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	AE.AEENDTC,
2.5		○ Absent *(0)* ○ Mild *(1)* ○ Moderate *(2)* ○ Severe *(3)* ○ Life Threatening *(4)* ○ Fatal *(5)*	AE.AETOXGR
2.6		○ No *(N)* ○ Yes *(Y)*	AE.AESER
2.7		☐ No *(N)* ☐ Yes *(Y)*	AE.AESCONG
2.8		☐ No *(N)* ☐ Yes *(Y)*	AE.AESDISAB
2.9		☐ No *(N)* ☐ Yes *(Y)*	AE.AESDTH
2.10		☐ No *(N)* ☐ Yes *(Y)*	AE.AESHOSP
2.11		☐ No *(N)* ☐ Yes *(Y)*	AE.AESLIFE
2.12		☐ No *(N)* ☐ Yes *(Y)*	AE.AESOD
2.13		☐ No *(N)* ☐ Yes *(Y)*	AE.AESMIE

		☐ Yes *(Y)*	

Adverse Events

Ref	CRF Question	Data Collected	SDTM Annotations
2.14		☐ No *(N)* ☐ Yes *(Y)*	AE.AECONTRT
2.15		○ No *(N)* ○ Yes *(Y)*	AE.AEREL
2.16		○ 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		○ 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		○ 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		○ No *(N)* ○ Yes *(Y)*	SUPPAE.QVAL, SUPPAE.QLABEL='Dose Limiting Toxicity'

ECG Test Results

Ref	CRF Question	Data Collected	SDTM Annotations
1.1		○ No *(N)* ○ Yes *(Y)*	EG.NOT,
1.2		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	EG.EGSTDTC,
1.3		HH:MM *Time* *Always collect times as HH:MM and store times as ISO8601 in SDTM.*	EG.EGSTDTC,
1.4		○ Normal *(NORMAL)* ○ Abnormal *(ABNORMAL)*	EG.EGORRES
2.1		○ No *(N)* ○ Yes *(Y)*	SUPPEG.QVAL, SUPPEG.QLABEL='ECG clinically significant'

Death

Ref	CRF Question	Data Collected	SDTM Annotations
1.1		○ No *(N)* ○ Yes *(Y)*	DD.NOT,
1.2		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	DD.DDDTC
2.1		DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*	DM.DTHDTC
3.1		*Text*	DD.DDORRES, DDTEST='Primary Diagnosis'
3.2		*Text*	DD.DDORRES, DDTEST='Secondary Diagnosis'
3.3		○ Home *(HOME)* ○ Hospital *(HOSPITAL)* ○ Nursing/Rehabilitation Home *(NURSING/REHABILITATION HOME)*	DD.DDORRES, DDTEST='What is the location of death'
3.4		*Text*	DD.DDORRES, DDTEST='Was Death Witnessed'