

Study

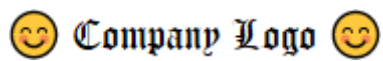
CRF Specification for Test Trial

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		<div>DD-MMM-YYYY</div> <i>Date</i> <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>	DM.BRTHDTC,
1.2		<input type="radio"/> Female (F) <input type="radio"/> Male (M) <input type="radio"/> U; UNK; Unknown (U) <input type="radio"/> UNDIFFERENTIATED <i>(UNDIFFERENTIATED)</i>	DM.SEX
1.3		<input type="radio"/> HISPANIC OR LATINO <i>(HISPANIC OR LATINO)</i> <input type="radio"/> NOT HISPANIC OR LATINO <i>(NOT HISPANIC OR LATINO)</i> <input type="radio"/> Not reported <i>(NOT REPORTED)</i> <input type="radio"/> U; UNK; Unknown <i>(UNKNOWN)</i>	DM.ETHNIC
1.4		<input type="radio"/> AMERICAN INDIAN OR ALASKA NATIVE <input type="radio"/> ASIAN <input type="radio"/> BLACK OR AFRICAN AMERICAN <input type="radio"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="radio"/> NOT REPORTED <input type="radio"/> UNKNOWN <input type="radio"/> 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		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMOCCUR, CMPRESP='Y', CMTRT='ARBs'
1.2		<input type="radio"/> Contraindication (CONTRAINDICATION) <input type="radio"/> Treatment not indicated (TREATMENT NOT INDICATED) <input type="radio"/> Cost (COST) <input type="radio"/> Unknown (UNKNOWN)	CM.CMREASND, CMPRESP='Y', CMTRT='ARBs'
1.3		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMOCCUR, CMPRESP='Y', CMTRT='ARNIs'
1.4		<input type="radio"/> Contraindication (CONTRAINDICATION) <input type="radio"/> Treatment not indicated (TREATMENT NOT INDICATED) <input type="radio"/> Cost (COST) <input type="radio"/> Unknown (UNKNOWN) <input type="radio"/> Cost 2 (COST2) <input type="radio"/> Unknown 2 (UNKNOWN2)	CM.CMREASND, CMPRESP='Y', CMTRT='ARNIs'
1.5		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMOCCUR, CMPRESP='Y', CMTRT='Aldosterone Antagonists'
1.6		<input type="radio"/> Contraindication (CONTRAINDICATION) <input type="radio"/> Treatment not indicated (TREATMENT NOT INDICATED) <input type="radio"/> Cost (COST) <input type="radio"/> Unknown (UNKNOWN)	CM.CMREASND, CMPRESP='Y', CMTRT='Aldosterone Antagonists'
1.7		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMOCCUR, 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		<input type="radio"/> Contraindication <i>(CONTRAINDICATION)</i> <input type="radio"/> Treatment not indicated <i>(TREATMENT NOT INDICATED)</i> <input type="radio"/> Cost <i>(COST)</i> <input type="radio"/> Unknown <i>(UNKNOWN)</i>	CM.CMREASND, CMPRESP='Y', CMTRT='Hydralazine'
1.9		<input type="radio"/> No <i>(N)</i> <input type="radio"/> Yes <i>(Y)</i>	CM.CMOCCUR, CMPRESP='Y', CMTRT='Diuretics'
1.10		<input type="radio"/> Contraindication <i>(CONTRAINDICATION)</i> <input type="radio"/> Treatment not indicated <i>(TREATMENT NOT INDICATED)</i> <input type="radio"/> Cost <i>(COST)</i> <input type="radio"/> Unknown <i>(UNKNOWN)</i>	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		<input type="text"/> Text	CM.CMTRT
1.2		<input type="text"/> Integer	CM.CMDOSE
1.3		<input type="radio"/> mcg (ug) <input type="radio"/> mg (mg) <input type="radio"/> g (g) <input type="radio"/> mL (mL) <input type="radio"/> Application (APPLICATION) <input type="radio"/> International Unit (IU) (IU) <input type="radio"/> Tablet (TABLET) <input type="radio"/> Capsule (CAPSULE) <input type="radio"/> Other (OTHER)	CM.CMDOSU,
1.4		<input type="radio"/> BD; Twice per day (BID) <input type="radio"/> As needed (PRN)	CM.CMDOSFRQ
1.5		<input type="radio"/> ORAL <input type="radio"/> SUBCUTANEOUS <input type="radio"/> TOPICAL <input type="radio"/> TRANSDERMAL	CM.CMROUTE,
1.6		<input type="text" value="DD-MMM-YYYY"/> Date Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.	CM.CMSTDTC
1.7		<input type="radio"/> AFTER <input type="radio"/> BEFORE <input type="radio"/> COINCIDENT <input type="radio"/> DURING <input type="radio"/> DURING/AFTER <input type="radio"/> ONGOING <input type="radio"/> UNKNOWN	CM.CMENRTPT
1.8		<input type="text" value="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		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	SUPPCM.QVAL, SUPPCM.QLABEL='Was medication given at recom. regimen'
2.2		<input type="text"/> Text	SUPPCM.QVAL, SUPPCM.QLABEL='Why the medication not given at regimen'

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected	SDTM Annotations
1.1		<input type="radio"/> No (<i>N</i>) <input type="radio"/> Yes (<i>Y</i>)	CM.CMOCCUR, CMTRT='ANTIPSORIATIC', CMPRESP='Y', CMSTRF='BEFORE'
1.2		<input type="radio"/> Biologic (<i>BIOLOGIC</i>) <input type="radio"/> Non-Biologic (<i>NON-BIOLOGIC</i>) <input type="radio"/> Phototherapy (<i>PHOTOTHERAPY</i>)	CM.CMSCAT,
1.3		<input type="text"/> <i>Text</i>	CM.CMTRT,
1.4		<input type="radio"/> ORAL <input type="radio"/> SUBCUTANEOUS <input type="radio"/> TOPICAL <input type="radio"/> TRANSDERMAL	CM.CMROUTE,
1.5		<input type="text"/> <i>Text</i>	CM.CMDOSTXT, CMDOSE if all values of CMDOSTXT are numeric
1.6		<input type="radio"/> mcg (<i>ug</i>) <input type="radio"/> mg (<i>mg</i>) <input type="radio"/> g (<i>g</i>) <input type="radio"/> mL (<i>mL</i>) <input type="radio"/> Application (<i>APPLICATION</i>) <input type="radio"/> International Unit (IU) (<i>IU</i>) <input type="radio"/> Tablet (<i>TABLET</i>) <input type="radio"/> Capsule (<i>CAPSULE</i>) <input type="radio"/> Other (<i>OTHER</i>)	CM.CMDOSU,
2.1		<input type="radio"/> Single-dose pen (<i>SINGLE-DOSE PEN</i>) <input type="radio"/> Multiple-dose pen (<i>MULTIPLE-DOSE PEN</i>) <input type="radio"/> Pre-filled syringe (<i>PRE-FILLED SYRINGE</i>) <input type="radio"/> Syringe (<i>SYRINGE</i>) <input type="radio"/> Not Applicable (<i>NOT APPLICABLE</i>)	SUPPCM.QVAL, SUPPCM.QLABEL='Device Identifier'
3.1		<input type="text"/> DD-MMM-YYYY <i>Date</i> <i>Always collect dates as DD- MMM-YYYY and store dates as ISO8601 in SDTM.</i>	CM.CMSTDTC,

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected	SDTM Annotations
3.2		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMENRTPT, If Yes, CMENRTPT='ONGOING'. If No, CMENRF=blank
3.3		<div>DD-MMM-YYYY</div> <div>Date</div> <p>Always collect dates as DD- MMM-YYYY and store dates as ISO8601 in SDTM.</p>	CM.CMENDTC,
4.1		<input type="radio"/> Inadequate efficiency (INADEQUATE EFFICACY) <input type="radio"/> Adverse event (ADVERSE EVENT) <input type="radio"/> 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		<input type="radio"/> FACE (<i>FACE</i>) <input type="radio"/> GENITALIA (<i>GENITALIA</i>) <input type="radio"/> Hand (<i>HAND</i>) <input type="radio"/> HEAD (<i>HEAD</i>) <input type="radio"/> Lower Extremity (<i>LIMB, LOWER</i>) <input type="radio"/> Upper Extremity (<i>LIMB, UPPER</i>) <input type="radio"/> SCALP (<i>SCALP</i>) <input type="radio"/> Torso (<i>TRUNK</i>)	QS.QSLOC, QSTEST='Lesion Identification'
1.2		<input type="radio"/> LEFT <input type="radio"/> RIGHT <input type="radio"/> NOT APPLICABLE	QS.QSLAT, QSTEST='Lesion Identification'
1.3		<input type="radio"/> ANTERIOR <input type="radio"/> POSTERIOR <input type="radio"/> NOT APPLICABLE	QS.QSDIR, QSTEST='Lesion Identification'

Adverse Events

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

Adverse Events

Ref	CRF Question	Data Collected	SDTM Annotations
2.14		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AECONTRT
2.15		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	AE.AEREL
2.16		<input type="radio"/> Adjunct Therapy (ADJUNCT THERAPY) <input type="radio"/> Concomitant Therapy (CONCOMITANT THERAPY) <input type="radio"/> Study Device (STUDY DEVICE) <input type="radio"/> Study Disease (STUDY DISEASE) <input type="radio"/> Study Procedure (STUDY PROCEDURE) <input type="radio"/> Other Medical Condition (OTHER MEDICAL CONDITION)	AE.AERELNST
2.17		<input type="radio"/> Fatal (FATAL) <input type="radio"/> Not recovered/not resolved (NOT RECOVERED/NOT RESOLVED) <input type="radio"/> Recovered/resolved with sequelae (RECOVERED/RESOLVED WITH SEQUELAE) <input type="radio"/> Recovered/resolved (RECOVERED/RESOLVED) <input type="radio"/> Recovering/resolving (RECOVERING/RESOLVING) <input type="radio"/> Unknown (C49496)	AE.AEOUT
2.18		<input type="radio"/> Dose not changed (DOSE NOT CHANGED) <input type="radio"/> Dose reduced (DOSE REDUCED) <input type="radio"/> Dose increased (DOSE INCREASED) <input type="radio"/> Drug interrupted (DRUG INTERRUPTED) <input type="radio"/> Drug withdrawn (DRUG WITHDRAWN) <input type="radio"/> Not applicable (NOT APPLICABLE) <input type="radio"/> Unknown (UNKNOWN)	AE.AEACN
3.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	SUPPAE.QVAL, SUPPAE.QLABEL='Dose Limiting Toxicity'

ECG Test Results

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

Death

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

