

Study

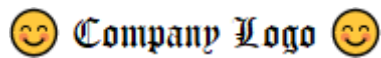
CRF Specification for Test Trial

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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Body Sites of Psoriasis Involvement at Baseline

Death

Demographics

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Subject eligibility

Subject eligibility

Ref	CRF Question	Data Collected	SDTM Annotations
1.1	Does the subject meet all inclusion criteria and none of the exclusion criteria?	<input type="radio"/> Yes (Y) <input type="radio"/> No (N)	SUPPIE.QVAL, SUPPDM.QNAM=IEYN, SUPPDM.QLABEL='All inclusion/exclusion criteria met'
2.1	Seq. no.	<input type="text"/> <i>Integer</i>	IE.IESPID
2.2	Inclusion criteria not met <i>Tick all that apply</i>	<input type="checkbox"/> Inclusion 1 (INCL01) <input type="checkbox"/> Inclusion 2 (INCL02) <input type="checkbox"/> Inclusion 3 (INCL03) <input type="checkbox"/> Inclusion 4 (INCL04) <input type="checkbox"/> Inclusion 5 (INCL05) <input type="checkbox"/> Inclusion 6 (INCL06) <input type="checkbox"/> Inclusion 7 (INCL07) <input type="checkbox"/> Inclusion 8 (INCL08) <input type="checkbox"/> Inclusion 9 (INCL09) <input type="checkbox"/> 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.	<input type="text"/> <i>Integer</i>	IE.IESPID
3.2	Exclusion criteria met <i>Tick all that apply</i>	<input type="checkbox"/> Exclusion 1 (EXCL01) <input type="checkbox"/> Exclusion 2 (EXCL02) <input type="checkbox"/> Exclusion 3 (EXCL03) <input type="checkbox"/> Exclusion 4 (EXCL04) <input type="checkbox"/> Exclusion 5 (EXCL05) <input type="checkbox"/> Exclusion 6 (EXCL06) <input type="checkbox"/> Exclusion 7 (EXCL07) <input type="checkbox"/> Exclusion 8 (EXCL08) <input type="checkbox"/> Exclusion 9 (EXCL09) <input type="checkbox"/> 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	<div>DD-MMM-YYYY</div> <p>Date</p> <p>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</p>	DM.BRTHDTC, Partial dates are to be recorded according to ISO 8601
1.2	Sex	<p><input type="radio"/> Female (F)</p> <p><input type="radio"/> Male (M)</p> <p><input type="radio"/> U; UNK; Unknown (U)</p> <p><input type="radio"/> UNDIFFERENTIATED (UNDIFFERENTIATED)</p>	DM.SEX
1.3	Ethnicity	<p><input type="radio"/> HISPANIC OR LATINO (HISPANIC OR LATINO)</p> <p><input type="radio"/> NOT HISPANIC OR LATINO (NOT HISPANIC OR LATINO)</p> <p><input type="radio"/> Not reported (NOT REPORTED)</p> <p><input type="radio"/> U; UNK; Unknown (UNKNOWN)</p>	DM.ETHNIC
1.4	Race	<p><input type="radio"/> AMERICAN INDIAN OR ALASKA NATIVE</p> <p><input type="radio"/> ASIAN</p> <p><input type="radio"/> BLACK OR AFRICAN AMERICAN</p> <p><input type="radio"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER</p> <p><input type="radio"/> NOT REPORTED</p> <p><input type="radio"/> UNKNOWN</p> <p><input type="radio"/> WHITE</p>	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?	<input type="radio"/> No (N) <input type="radio"/> 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	<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, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARBs'
1.3	Were any angiotensin receptor/neprilysin inhibitors (ARNIs) taken?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs'
1.4	If No, provide reason for not prescribing ARNIs	<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, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs'
1.5	Were any aldosterone antagonists taken?	<input type="radio"/> No (N) <input type="radio"/> 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	<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, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Aldosterone Antagonists'
1.7	Was any hydralazine taken?	<input type="radio"/> No (N) <input type="radio"/> 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	<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, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Hydralazine'
1.9	Were any diuretics taken?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Diuretics'
1.10	If No, provide reason for not prescribing diuretics	<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, 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?	<input type="text"/> Text	CM.CMTRT
1.2	What was the individual dose of the medication per administration?	<input type="text"/> Integer	CM.CMDOSE
1.3	What is the unit of the medication per administration?	<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 (<i>IU</i>) (<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, CM.CMCAT='ANTIPSORIATIC'
1.4	What was the frequency of the medication?	<input type="radio"/> BD; Twice per day (<i>BID</i>) <input type="radio"/> As needed (<i>PRN</i>)	CM.CMDOSFRQ
1.5	What was the route of administration of the medication?	<input type="radio"/> ORAL <input type="radio"/> SUBCUTANEOUS <input type="radio"/> TOPICAL <input type="radio"/> TRANSDERMAL	CM.CMROUTE, CM.CMCAT='ANTIPSORIATIC'
1.6	Start Date	<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	Is the medication ongoing?	<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	End Date	<input type="text" value="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?	<input type="radio"/> No (<i>N</i>) <input type="radio"/> Yes (<i>Y</i>)	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?	<input type="text"/> <i>Text</i>	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?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	CM.CMOCCUR, CMCAT='ANTIPSORIATIC', CMTRT='ANTIPSORIATIC', CMPRESP='Y', CMSTRF='BEFORE'
1.2	What is the subcategory for the treatment?	<input type="radio"/> Biologic (BIOLOGIC) <input type="radio"/> Non-Biologic (NON-BIOLOGIC) <input type="radio"/> Phototherapy (PHOTOTHERAPY)	CM.CMSCAT, CMCAT='ANTIPSORIATIC'
1.3	What was the name of the treatment?	<input type="text"/> <i>Text</i>	CM.CMTRT, CMCAT='ANTIPSORIATIC'
1.4	What was the route of administration of the medication?	<input type="radio"/> ORAL <input type="radio"/> SUBCUTANEOUS <input type="radio"/> TOPICAL <input type="radio"/> TRANSDERMAL	CM.CMROUTE, CM.CMCAT='ANTIPSORIATIC'
1.5	If the treatment was systemic, what was the individual dose?	<input type="text"/> <i>Text</i>	CM.CMDOSTXT, CMCAT='ANTIPSORIATIC', CMDOSE if all values of CMDOSTXT are numeric
1.6	What is the unit of the medication per administration?	<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, CM.CMCAT='ANTIPSORIATIC'
2.1	If the medication was a biologic, what device was used for drug administration?	<input type="radio"/> Single-dose pen (SINGLE-DOSE PEN) <input type="radio"/> Multiple-dose pen (MULTIPLE-DOSE PEN) <input type="radio"/> Pre-filled syringe (PRE-FILLED SYRINGE) <input type="radio"/> Syringe (SYRINGE) <input type="radio"/> Not Applicable (NOT APPLICABLE)	SUPPCM.QVAL, SUPPCM.QNAM='SPDEVID', SUPPCM.QLABEL='Device Identifier'
3.1	Start Date	<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, CMCAT='ANTIPSORIATIC'
3.2	Is the medication ongoing?	<input type="radio"/> No (N) <input type="radio"/> 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	<div>DD-MMM-YYYY</div> <p>Date</p> <p>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</p>	CM.CMENDTC, CM.CMCAT='ANTIPSORIATIC'
4.1	What was the reason for treatment discontinuation?	<p><input type="radio"/> Inadequate efficiency (INADEQUATE EFFICACY)</p> <p><input type="radio"/> Adverse event (ADVERSE EVENT)</p> <p><input type="radio"/> Other-not related to efficacy/adverse event (OTHER-NOT RELATED TO EFFICACY/ADVERSE EVENTS)</p>	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?	<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, QSTESTCD='LESIDENT',QSTEST='Lesion Identification'
1.2	If applicable, what was the laterality of the anatomical location?	<input type="radio"/> LEFT <input type="radio"/> RIGHT <input type="radio"/> NOT APPLICABLE	QS.QSLAT, QSTESTCD='LESIDENT', QSTEST='Lesion Identification'
1.3	If applicable, what was the directionality of the anatomical location?	<input type="radio"/> ANTERIOR <input type="radio"/> POSTERIOR <input type="radio"/> 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?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	NOT SUBMITTED
1.2	AE Group ID	<input type="text"/> Text	AE.AEGRPID
1.3	What is the adverse event term?	<input type="text"/> Text	AE.AETERM
2.1	AE Identifier	<input type="text"/> Integer	AE.AESPID
2.2	What is the date the adverse event started?	<input type="text" value="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?	<input type="text"/> Text	AE.AEENTPT, If Yes, AE.AEENTPT=ONGOING. If No, AE.AEENTPT=BEFORE
2.4	End date	<input type="text" value="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?	<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	Is the adverse event serious?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	AE.AESER
2.7	Congenital Anomaly or Birth Defect	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AESCONG
2.8	Significant Disability	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AESDISAB
2.9	Death	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AESDTH
2.10	Hospitalization	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AESHOSP
2.11	Life Threatening	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AESLIFE
2.12	Occurs with Overdose	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AESOD
2.13	Other Medically Important Event	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AESMIE
2.14	Concomitant or Additional Treatment Given	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)	AE.AECONTRT

Adverse Events

Ref	CRF Question	Data Collected	SDTM Annotations
2.15	Is this event related to study treatment?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	AE.AEREL
2.16	Relationship to Non-Study Treatment	<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	What was the outcome of this adverse event?	<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	What action was taken with study treatment?	<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	Is this event a dose limiting toxicity?	<input type="radio"/> No (N) <input type="radio"/> 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?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	NOT SUBMITTED
2.1	What was the ECG date?	<div>DD-MMM-YYYY</div> <i>Date</i> 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?	<div>HH:MM</div> <i>Time</i> 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?	<input type="radio"/> Normal (NORMAL) <input type="radio"/> Abnormal (ABNORMAL)	EG.EGORRES
3.1	Was the ECG clinically significant?	<input type="radio"/> No (N) <input type="radio"/> 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?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)	NOT SUBMITTED
2.1	Collection Date	<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
3.1	Death Date	<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.DTHDTC
4.1	What is the primary cause of death?	<div></div> <i>Text</i>	DD.DDORRES, DD.DDTESTCD='DIAGPRIM', DD.DDTEST='Primary Diagnosis'
4.2	What is the secondary cause of death?	<div></div> <i>Text</i>	DD.DDORRES, DD.DDTESTCD='DIAGSEC', DD.DDTEST='Secondary Diagnosis'
4.3	What is the location of death?	<input type="radio"/> Home (HOME) <input type="radio"/> Hospital (HOSPITAL) <input type="radio"/> Nursing/Rehabilitation Home (NURSING/REHABILITATION HOME)	DD.DDORRES, DD.DDTESTCD='LOCPTH', DD.DDTEST='What is the location of death'
4.4	Was the death witnessed?	<div></div> <i>Text</i>	DD.DDORRES, DD.DDTESTCD='DTHWIT', DD.DDTEST='Was Death Witnessed'