

Study

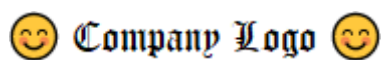
CRF Specification for Test Trial

Selection of CRF forms available at CDISC

Protocol Name:

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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

Subject eligibility

Ref	CRF Question	Data Collected
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)
2.1	Seq. no.	<input type="text"/> <i>Integer</i>
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)
3.1	Seq. no.	<input type="text"/> <i>Integer</i>
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)

Demographics

Ref	CRF Question	Data Collected
1.1	Birth Date	<div>DD-MMM-YYYY</div> <div>Date</div> <p>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</p>
1.2	Sex	<p> <input type="radio"/> Female (F) <input type="radio"/> Male (M) <input type="radio"/> U; UNK; Unknown (U) <input type="radio"/> UNDIFFERENTIATED (UNDIFFERENTIATED) </p>
1.3	Ethnicity	<p> <input type="radio"/> HISPANIC OR LATINO (HISPANIC OR LATINO) <input type="radio"/> NOT HISPANIC OR LATINO (NOT HISPANIC OR LATINO) <input type="radio"/> Not reported (NOT REPORTED) <input type="radio"/> U; UNK; Unknown (UNKNOWN) </p>
1.4	Race	<p> <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 </p>

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
1.1	Were any angiotensin-converting enzyme (ACE) inhibitors taken?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.3	Were any angiotensin receptor/neprilysin inhibitors (ARNIs) taken?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.5	Were any aldosterone antagonists taken?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.7	Was any hydralazine taken?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.9	Were any diuretics taken?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)

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
1.1	What was the medication name?	<input type="text"/> Text
1.2	What was the individual dose of the medication per administration?	<input type="text"/> Integer
1.3	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)
1.4	What was the frequency of the medication?	<input type="radio"/> BD; Twice per day (BID) <input type="radio"/> As needed (PRN)
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
1.6	Start Date	<input type="text"/> DD-MMM-YYYY Date Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
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
1.8	End Date	<input type="text"/> DD-MMM-YYYY Date Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
2.1	If applicable, was the medication given at the recommended regimen?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
2.2	If applicable, why was the medication not given at the recommended regimen?	<input type="text"/> Text

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected
1.1	Has the subject had any psoriasis treatments before the study start?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.3	What was the name of the treatment?	<input type="text"/> Text
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
1.5	If the treatment was systemic, what was the individual dose?	<input type="text"/> Text
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)
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)
3.1	Start Date	<input type="text"/> DD-MMM-YYYY Date Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
3.2	Is the medication ongoing?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
3.3	End Date	<input type="text"/> DD-MMM-YYYY Date Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
4.1	What was the reason for treatment discontinuation?	<input type="radio"/> Inadequate efficacy (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)

Body Sites of Psoriasis Involvement at Baseline

CRF Instructions: Use one page per affected area

Ref	CRF Question	Data Collected
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>)
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
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

Adverse Events

Ref	CRF Question	Data Collected
1.1	Were any adverse events experienced?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
1.2	AE Group ID	<input type="text"/> Text
1.3	What is the adverse event term?	<input type="text"/> Text
2.1	AE Identifier	<input type="text"/> Integer
2.2	What is the date the adverse event started?	<input type="text"/> DD-MMM-YYYY Date <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
2.3	Is the adverse event still ongoing?	<input type="text"/> Text
2.4	End date	<input type="text"/> DD-MMM-YYYY Date <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
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)
2.6	Is the adverse event serious?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
2.7	Congenital Anomaly or Birth Defect	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.8	Significant Disability	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.9	Death	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.10	Hospitalization	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.11	Life Threatening	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.12	Occurs with Overdose	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.13	Other Medically Important Event	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.14	Concomitant or Additional Treatment Given	<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.15	Is this event related to study treatment?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)

Adverse Events

Ref	CRF Question	Data Collected
2.16	Relationship to Non-Study Treatment	<input type="radio"/> Adjunct Therapy (<i>ADJUNCT THERAPY</i>) <input type="radio"/> Concomitant Therapy (<i>CONCOMITANT THERAPY</i>) <input type="radio"/> Study Device (<i>STUDY DEVICE</i>) <input type="radio"/> Study Disease (<i>STUDY DISEASE</i>) <input type="radio"/> Study Procedure (<i>STUDY PROCEDURE</i>) <input type="radio"/> Other Medical Condition (<i>OTHER MEDICAL CONDITION</i>)
2.17	What was the outcome of this adverse event?	<input type="radio"/> Fatal (<i>FATAL</i>) <input type="radio"/> Not recovered/not resolved (<i>NOT RECOVERED/NOT RESOLVED</i>) <input type="radio"/> Recovered/resolved with sequelae (<i>RECOVERED/RESOLVED WITH SEQUELAE</i>) <input type="radio"/> Recovered/resolved (<i>RECOVERED/RESOLVED</i>) <input type="radio"/> Recovering/resolving (<i>RECOVERING/RESOLVING</i>) <input type="radio"/> Unknown (<i>C49496</i>)
2.18	What action was taken with study treatment?	<input type="radio"/> Dose not changed (<i>DOSE NOT CHANGED</i>) <input type="radio"/> Dose reduced (<i>DOSE REDUCED</i>) <input type="radio"/> Dose increased (<i>DOSE INCREASED</i>) <input type="radio"/> Drug interrupted (<i>DRUG INTERRUPTED</i>) <input type="radio"/> Drug withdrawn (<i>DRUG WITHDRAWN</i>) <input type="radio"/> Not applicable (<i>NOT APPLICABLE</i>) <input type="radio"/> Unknown (<i>UNKNOWN</i>)
3.1	Is this event a dose limiting toxicity?	<input type="radio"/> No (<i>N</i>) <input type="radio"/> Yes (<i>Y</i>)

ECG Test Results

Ref	CRF Question	Data Collected
1.1	Was the ECG performed?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
2.1	What was the ECG date?	<div>DD-MMM-YYYY</div> <div>Date</div> <p><i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i></p>
2.2	What was the ECG time?	<div>HH:MM</div> <div>Time</div> <p><i>Always collect times as HH:MM and store times as ISO8601 in SDTM.</i></p>
2.3	What was the result of the ECG?	<input type="radio"/> Normal (NORMAL) <input type="radio"/> Abnormal (ABNORMAL)
3.1	Was the ECG clinically significant?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)

Death

Ref	CRF Question	Data Collected
1.1	Were any death detail assessments collected?	<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
2.1	Collection Date	<div>DD-MMM-YYYY</div> <div>Date</div> <p><i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i></p>
3.1	Death Date	<div>DD-MMM-YYYY</div> <div>Date</div> <p><i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i></p>
4.1	What is the primary cause of death?	<div></div> <div>Text</div>
4.2	What is the secondary cause of death?	<div></div> <div>Text</div>
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)
4.4	Was the death witnessed?	<div></div> <div>Text</div>