

# Study

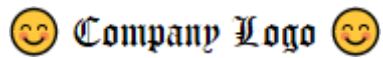
## CRF Specification for Test Trial

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
1.1		<div>DD-MMM-YYYY <i>Date</i></div> <p><i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i></p>
1.2		<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		<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		<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		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.3		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.5		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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)
1.7		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
1.8		<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		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
1.10		<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		<input type="text"/> Text
1.2		<input type="text"/> Integer
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)
1.4		<input type="radio"/> BD; Twice per day (BID) <input type="radio"/> As needed (PRN)
1.5		<input type="radio"/> ORAL <input type="radio"/> SUBCUTANEOUS <input type="radio"/> TOPICAL <input type="radio"/> TRANSDERMAL
1.6		<input type="text"/> DD-MMM-YYYY Date  Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
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
1.8		<input type="text"/> DD-MMM-YYYY Date  Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
2.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
2.2		<input type="text"/> Text

## Prior Psoriasis Treatments

Ref	CRF Question	Data Collected
1.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
1.2		<input type="radio"/> Biologic (BIOLOGIC) <input type="radio"/> Non-Biologic (NON-BIOLOGIC) <input type="radio"/> Phototherapy (PHOTOTHERAPY)
1.3		<input type="text"/> Text
1.4		<input type="radio"/> ORAL <input type="radio"/> SUBCUTANEOUS <input type="radio"/> TOPICAL <input type="radio"/> TRANSDERMAL
1.5		<input type="text"/> Text
1.6		<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		<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		<input type="text"/> DD-MMM-YYYY Date  Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
3.2		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
3.3		<input type="text"/> DD-MMM-YYYY Date  Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.
4.1		<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		<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		<input type="radio"/> LEFT <input type="radio"/> RIGHT <input type="radio"/> NOT APPLICABLE
1.3		<input type="radio"/> ANTERIOR <input type="radio"/> POSTERIOR <input type="radio"/> NOT APPLICABLE

## Adverse Events

Ref	CRF Question	Data Collected
1.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
1.2		<input type="text"/> Text
1.3		<input type="text"/> Text
2.1		<input type="text"/> Integer
2.2		<input type="text" value="DD-MMM-YYYY"/> Date  <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
2.3		<input type="text"/> Text
2.4		<input type="text" value="DD-MMM-YYYY"/> Date  <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
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)
2.6		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
2.7		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.8		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.9		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.10		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.11		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.12		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.13		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.14		<input type="checkbox"/> No (N) <input type="checkbox"/> Yes (Y)
2.15		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)



## Adverse Events

Ref	CRF Question	Data Collected
2.16		<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		<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		<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		<input type="radio"/> No ( <i>N</i> ) <input type="radio"/> Yes ( <i>Y</i> )

## ECG Test Results

Ref	CRF Question	Data Collected
1.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
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>
1.3		<div>HH:MM</div> <i>Time</i>  <i>Always collect times as HH:MM and store times as ISO8601 in SDTM.</i>
1.4		<input type="radio"/> Normal (NORMAL) <input type="radio"/> Abnormal (ABNORMAL)
2.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)

## Death

Ref	CRF Question	Data Collected
1.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
1.2		<div>DD-MMM-YYYY</div> <div>Date</div> <p>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</p>
2.1		<div>DD-MMM-YYYY</div> <div>Date</div> <p>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</p>
3.1		<div></div> <div>Text</div>
3.2		<div></div> <div>Text</div>
3.3		<input type="radio"/> Home (HOME) <input type="radio"/> Hospital (HOSPITAL) <input type="radio"/> Nursing/Rehabilitation Home (NURSING/REHABILITATION HOME)
3.4		<div></div> <div>Text</div>

