# Study

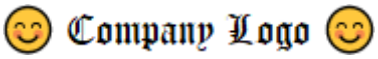
# CRF Specification for Test Trial

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 | | | ✔ |

# Table of Contents

## Subject eligibility

| Ref | CRF Question | Data Collected | SDTM Annotations |
|---|---|---|---|
| 1.1 | Does the subject meet all inclusion criteria and none of the exclusion criteria? | ○ Yes *(Y)*<br>○ No *(N)* | SUPPIE.QVAL,<br>SUPPDM.QNAM=IEYN,<br>SUPPDM.QLABEL='All inclusion/exclusion criteria met' |
| 2.1 | Seq. no. | *Integer* | IE.IESPID |
| 2.2 | Inclusion criteria not met<br>*Tick all that apply* | ☐ Inclusion 1 *(INCL01)*<br>☐ Inclusion 2 *(INCL02)*<br>☐ Inclusion 3 *(INCL03)*<br>☐ Inclusion 4 *(INCL04)*<br>☐ Inclusion 5 *(INCL05)*<br>☐ Inclusion 6 *(INCL06)*<br>☐ Inclusion 7 *(INCL07)*<br>☐ Inclusion 8 *(INCL08)*<br>☐ Inclusion 9 *(INCL09)*<br>☐ Inclusion 10 *(INCL10)* | IE.IETESTCD,<br>IE.IETEST=TI.IETEST,<br>IE.IECAT=TI.IECAT.<br>If failed inclusion criteria,<br>IE.IEORRES=N, IE.IESTRESC=N.<br>If failed exclusion criteria,<br>IE.IEORRES=Y, IE.IESTRESC=Y |
| 3.1 | Seq. no. | *Integer* | IE.IESPID |
| 3.2 | Exclusion criteria met<br>*Tick all that apply* | ☐ Exclusion 1 *(EXCL01)*<br>☐ Exclusion 2 *(EXCL02)*<br>☐ Exclusion 3 *(EXCL03)*<br>☐ Exclusion 4 *(EXCL04)*<br>☐ Exclusion 5 *(EXCL05)*<br>☐ Exclusion 6 *(EXCL06)*<br>☐ Exclusion 7 *(EXCL07)*<br>☐ Exclusion 8 *(EXCL08)*<br>☐ Exclusion 9 *(EXCL09)*<br>☐ Exclusion 10 *(EXCL10)* | IE.IETESTCD,<br>IE.IETEST= TI.IETEST,<br>IE.IECAT=TI.IECAT.<br>If failed inclusion criteria,<br>IE.IEORRES=N, IE.IESTRESC=N.<br>If failed exclusion criteria,<br>IE.IEORRES=Y, IE.IESTRESC=Y |

## Demographics

| Ref | CRF Question | Data Collected | SDTM Annotations |
|---|---|---|---|
| 1.1 | Birth Date | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | DM.BRTHDTC,<br>Partial dates are to be recorded according to ISO 8601 |
| 1.2 | Sex | ○ Female *(F)*<br>○ Male *(M)*<br>○ U; UNK; Unknown *(U)*<br>○ UNDIFFERENTIATED *(UNDIFFERENTIATED)* | DM.SEX |
| 1.3 | Ethnicity | ○ HISPANIC OR LATINO *(HISPANIC OR LATINO)*<br>○ NOT HISPANIC OR LATINO *(NOT HISPANIC OR LATINO)*<br>○ Not reported *(NOT REPORTED)*<br>○ U; UNK; Unknown *(UNKNOWN)* | DM.ETHNIC |
| 1.4 | Race | ○ AMERICAN INDIAN OR ALASKA NATIVE<br>○ ASIAN<br>○ BLACK OR AFRICAN AMERICAN<br>○ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER<br>○ NOT REPORTED<br>○ UNKNOWN<br>○ 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 | Were any angiotensin-converting enzyme (ACE) inhibitors taken? | ○ No *(N)*<br>○ 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 | ○ Contraindication *(CONTRAINDICATION)*<br>○ Treatment not indicated *(TREATMENT NOT INDICATED)*<br>○ Cost *(COST)*<br>○ Unknown *(UNKNOWN)* | CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARBs' |
| 1.3 | Were any angiotensin receptor/neprilysin inhibitors (ARNIs) taken? | ○ No *(N)*<br>○ Yes *(Y)* | CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs' |
| 1.4 | If No, provide reason for not prescribing ARNIs | ○ Contraindication *(CONTRAINDICATION)*<br>○ Treatment not indicated *(TREATMENT NOT INDICATED)*<br>○ Cost *(COST)*<br>○ Unknown *(UNKNOWN)*<br>○ Cost 2 *(COST2)*<br>○ Unknown 2 *(UNKNOWN2)* | CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs' |
| 1.5 | Were any aldosterone antagonists taken? | ○ No *(N)*<br>○ 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 | ○ Contraindication *(CONTRAINDICATION)*<br>○ Treatment not indicated *(TREATMENT NOT INDICATED)*<br>○ Cost *(COST)*<br>○ Unknown *(UNKNOWN)* | CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Aldosterone Antagonists' |
| 1.7 | Was any hydralazine taken? | ○ No *(N)*<br>○ 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 | ○ Contraindication *(CONTRAINDICATION)*<br>○ Treatment not indicated *(TREATMENT NOT INDICATED)*<br>○ Cost *(COST)*<br>○ Unknown *(UNKNOWN)* | CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Hydralazine' |
| 1.9 | Were any diuretics taken? | ○ No *(N)*<br>○ Yes *(Y)* | CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Diuretics' |
| 1.10 | If No, provide reason for not prescribing diuretics | ○ Contraindication *(CONTRAINDICATION)*<br>○ Treatment not indicated *(TREATMENT NOT INDICATED)*<br>○ Cost *(COST)*<br>○ 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? | *Text* | CM.CMTRT |
| 1.2 | What was the individual dose of the medication per administration? | *Integer* | CM.CMDOSE |
| 1.3 | What is the unit of the medication per administration? | ○ mcg *(ug)*<br>○ mg *(mg)*<br>○ g *(g)*<br>○ Ml *(mL)*<br>○ Application *(APPLICATION)*<br>○ International Unit (IU) *(IU)*<br>○ Tablet *(TABLET)*<br>○ Capsule *(CAPSULE)*<br>○ Other *(OTHER)* | CM.CMDOSU,<br>CM.CMCAT='ANTIPSORIATIC' |
| 1.4 | What was the frequency of the medication? | ○ BD; Twice per day *(BID)*<br>○ As needed *(PRN)* | CM.CMDOSFRQ |
| 1.5 | What was the route of administration of the medication? | ○ ORAL<br>○ SUBCUTANEOUS<br>○ TOPICAL<br>○ TRANSDERMAL | CM.CMROUTE,<br>CM.CMCAT='ANTIPSORIATIC' |
| 1.6 | Start Date | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | CM.CMSTDTC |
| 1.7 | Is the medication ongoing? | ○ AFTER<br>○ BEFORE<br>○ COINCIDENT<br>○ DURING<br>○ DURING/AFTER<br>○ ONGOING<br>○ UNKNOWN | CM.CMENRTPT |
| 1.8 | End Date | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | CM.CMENDTC,<br>CM.CMCAT='ANTIPSORIATIC' |
| 2.1 | If applicable, was the medication given at the recommended regimen? | ○ No *(N)*<br>○ Yes *(Y)* | SUPPCM.QVAL,<br>SUPPCM.QNAM='CMRRGYN',<br>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? | *Text* | 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? | ○ No *(N)*<br>○ Yes *(Y)* | CM.CMOCCUR, CMCAT='ANTIPSORIATIC', CMTRT='ANTIPSORIATIC', CMPRESP='Y', CMSTRF='BEFORE' |
| 1.2 | What is the subcategory for the treatment? | ○ Biologic *(BIOLOGIC)*<br>○ Non-Biologic *(NON-BIOLOGIC)*<br>○ Phototherapy *(PHOTOTHERAPY)* | CM.CMSCAT, CMCAT='ANTIPSORIATIC' |
| 1.3 | What was the name of the treatment? | *Text* | CM.CMTRT, CMCAT='ANTIPSORIATIC' |
| 1.4 | What was the route of administration of the medication? | ○ ORAL<br>○ SUBCUTANEOUS<br>○ TOPICAL<br>○ TRANSDERMAL | CM.CMROUTE, CM.CMCAT='ANTIPSORIATIC' |
| 1.5 | If the treatment was systemic, what was the individual dose? | *Text* | CM.CMDOSTXT, CMCAT='ANTIPSORIATIC', CMDOSE if all values of CMDOSTXT are numeric |
| 1.6 | What is the unit of the medication per administration? | ○ mcg *(ug)*<br>○ mg *(mg)*<br>○ g *(g)*<br>○ Ml *(mL)*<br>○ Application *(APPLICATION)*<br>○ International Unit (IU) *(IU)*<br>○ Tablet *(TABLET)*<br>○ Capsule *(CAPSULE)*<br>○ Other *(OTHER)* | CM.CMDOSU, CM.CMCAT='ANTIPSORIATIC' |
| 2.1 | If the medication was a biologic, what device was used for drug administration? | ○ Single-dose pen *(SINGLE-DOSE PEN)*<br>○ Multiple-dose pen *(MULTIPLE-DOSE PEN)*<br>○ Pre-filled syringe *(PRE-FILLED SYRINGE)*<br>○ Syringe *(SYRINGE)*<br>○ Not Applicable *(NOT APPLICABLE)* | SUPPCM.QVAL, SUPPCM.QNAM='SPDEVID', SUPPCM.QLABEL='Device Identifier' |
| 3.1 | Start Date | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | CM.CMSTDTC, CMCAT='ANTIPSORIATIC' |
| 3.2 | Is the medication ongoing? | ○ No *(N)*<br>○ 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 | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | CM.CMENDTC, CM.CMCAT='ANTIPSORIATIC' |
| 4.1 | What was the reason for treatment discontinuation? | ○ Inadequate efficiacy *(INADEQUATE EFFICACY)*<br>○ Adverse event *(ADVERSE EVENT)*<br>○ Other-not related to efficacy/adverse event *(OTHER-NOT RELATED TO EFFICACY/ADVERSE EVENTS)* | 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? | ○ FACE *(FACE)*<br>○ GENITALIA *(GENITALIA)*<br>○ Hand *(HAND)*<br>○ HEAD *(HEAD)*<br>○ Lower Extremity *(LIMB, LOWER)*<br>○ Upper Extremity *(LIMB, UPPER)*<br>○ SCALP *(SCALP)*<br>○ Torso *(TRUNK)* | QS.QSLOC, QSTESTCD='LESIDENT',QSTEST='Lesion Identification' |
| 1.2 | If applicable, what was the laterality of the anatomical location? | ○ LEFT<br>○ RIGHT<br>○ NOT APPLICABLE | QS.QSLAT, QSTESTCD='LESIDENT', QSTEST='Lesion Identification' |
| 1.3 | If applicable, what was the directionality of the anatomical location? | ○ ANTERIOR<br>○ POSTERIOR<br>○ 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? | ○ No *(N)*<br>○ Yes *(Y)* | NOT SUBMITTED |
| 1.2 | AE Group ID | *Text* | AE.AEGRPID |
| 1.3 | What is the adverse event term? | *Text* | AE.AETERM |
| 2.1 | AE Identifier | *Integer* | AE.AESPID |
| 2.2 | What is the date the adverse event started? | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | AE.AESTDTC,<br>Partial dates are stored according to ISO8601 |
| 2.3 | Is the adverse event still ongoing? | *Text* | AE.AEENTPT,<br>If Yes, AE.AEENTPT=ONGOING.<br>If No, AE.AEENTPT=BEFORE |
| 2.4 | End date | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | AE.AEENDTC,<br>Partial dates are stored according to ISO8601 |
| 2.5 | What is the toxicity grade of the adverse event? | ○ Absent *(0)*<br>○ Mild *(1)*<br>○ Moderate *(2)*<br>○ Severe *(3)*<br>○ Life Threatening *(4)*<br>○ Fatal *(5)* | AE.AETOXGR |
| 2.6 | Is the adverse event serious? | ○ No *(N)*<br>○ Yes *(Y)* | AE.AESER |
| 2.7 | Congenital Anomaly or Birth Defect | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AESCONG |
| 2.8 | Significant Disability | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AESDISAB |
| 2.9 | Death | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AESDTH |
| 2.10 | Hospitalization | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AESHOSP |
| 2.11 | Life Threatening | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AESLIFE |
| 2.12 | Occurs with Overdose | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AESOD |
| 2.13 | Other Medically Important Event | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AESMIE |
| 2.14 | Concomitant or Additional Treament Given | ☐ No *(N)*<br>☐ Yes *(Y)* | AE.AECONTRT |

## Adverse Events

| Ref | CRF Question | Data Collected | SDTM Annotations |
|---|---|---|---|
| 2.15 | Is this event related to study treatment? | ○ No *(N)*<br>○ Yes *(Y)* | AE.AEREL |
| 2.16 | Relationship to Non-Study Treatment | ○ Adjunct Therapy *(ADJUNCT THERAPY)*<br>○ Concomitant Therapy *(CONCOMITANT THERAPY)*<br>○ Study Device *(STUDY DEVICE)*<br>○ Study Disease *(STUDY DISEASE)*<br>○ Study Procedure *(STUDY PROCEDURE)*<br>○ Other Medical Condition *(OTHER MEDICAL CONDITION)* | AE.AERELNST |
| 2.17 | What was the outcome of this adverse event? | ○ Fatal *(FATAL)*<br>○ Not recovered/not resolved *(NOT RECOVERED/NOT RESOLVED )*<br>○ Recovered/resolved with sequelae *(RECOVERED/RESOLVED WITH SEQUELAE )*<br>○ Recovered/resolved *(RECOVERED/RESOLVED)*<br>○ Recovering/resolving *(RECOVERING/RESOLVING )*<br>○ Unkmown *(C49496)* | AE.AEOUT |
| 2.18 | What action was taken with study treatment? | ○ Dose not changed *(DOSE NOT CHANGED)*<br>○ Dose reduced *(DOSE REDUCED)*<br>○ Dose increased *(DOSE INCREASED)*<br>○ Drug interrupted *(DRUG INTERRUPTED)*<br>○ Drug withdrawn *(DRUG WITHDRAWN)*<br>○ Not applicable *(NOT APPLICABLE)*<br>○ Unknown *(UNKNOWN)* | AE.AEACN |
| 3.1 | Is this event a dose limiting toxicity? | ○ No *(N)*<br>○ 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? | ○ No *(N)*<br>○ Yes *(Y)* | NOT SUBMITTED |
| 2.1 | What was the ECG date? | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | EG.EGSTDTC,<br>Date and time are to be combined into one variable according to ISO 8601 |
| 2.2 | What was the ECG time? | HH:MM<br>*Time*<br>*Always collect times as HH:MM and store times as ISO8601 in SDTM.* | EG.EGSTDTC,<br>Date and time are to be combined into one variable according to ISO 8601 |
| 2.3 | What was the result of the ECG? | ○ Normal *(NORMAL)*<br>○ Abnormal *(ABNORMAL)* | EG.EGORRES |
| 3.1 | Was the ECG clinically significant? | ○ No *(N)*<br>○ Yes *(Y)* | SUPPEG.QVAL,<br>SUPPEG.QNAM='EGCLSIG',<br>SUPPEG.QLABEL='ECG clinically significant' |

## Death

| Ref | CRF Question | Data Collected | SDTM Annotations |
|---|---|---|---|
| 1.1 | Were any death detail assessments collected? | ○ No *(N)*<br>○ Yes *(Y)* | NOT SUBMITTED |
| 2.1 | Collection Date | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | DD.DDDTC |
| 3.1 | Death Date | DD-MMM-YYYY<br>*Date*<br>*Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.* | DD.DTHDTC |
| 4.1 | What is the primary cause of death? | *Text* | DD.DDORRES,<br>DD.DDTESTCD='DIAGPRIM',<br>DD.DDTEST='Primary Diagnosis' |
| 4.2 | What is the secondary cause of death? | *Text* | DD.DDORRES,<br>DD.DDTESTCD='DIAGSEC',<br>DD.DDTEST='Secondary Diagnosis' |
| 4.3 | What is the location of death? | ○ Home *(HOME)*<br>○ Hospital *(HOSPITAL)*<br>○ Nursing/Rehabilitation Home *(NURSING/REHABILITATION HOME)* | DD.DDORRES,<br>DD.DDTESTCD='LOCDTH',<br>DD.DDTEST='What is the location of death' |
| 4.4 | Was the death witnessed? | *Text* | DD.DDORRES,<br>DD.DDTESTCD='DTHWIT',<br>DD.DDTEST='Was Death Witnessed' |