CRF Book

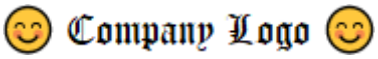
CRF Specification for Test Trial

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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	Site	Subject identifier	Screening

Demographics

Ref	CRF Question	Data Collected
1.1	Birth Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
1.2	Sex	○ Female *(F)* ○ Male *(M)* ○ U; UNK; Unknown *(U)* ○ UNDIFFERENTIATED *(UNDIFFERENTIATED)*
1.3	Ethnicity	○ HISPANIC OR LATINO *(HISPANIC OR LATINO)* ○ NOT HISPANIC OR LATINO *(NOT HISPANIC OR LATINO)* ○ Not reported *(NOT REPORTED)* ○ U; UNK; Unknown *(UNKNOWN)*
1.4	Race	○ AMERICAN INDIAN OR ALASKA NATIVE ○ ASIAN ○ BLACK OR AFRICAN AMERICAN ○ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER ○ NOT REPORTED ○ UNKNOWN ○ WHITE

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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?	○ No *(N)* ○ Yes *(Y)*
1.2	If No, provide reason for not prescribing ARBs	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*
1.3	Were any angiotensin receptor/neprilysin inhibitors (ARNIs) taken?	○ No *(N)* ○ Yes *(Y)*
1.4	If No, provide reason for not prescribing ARNIs	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)* ○ Cost 2 *(COST2)* ○ Unknown 2 *(UNKNOWN2)*
1.5	Were any aldosterone antagonists taken?	○ No *(N)* ○ Yes *(Y)*
1.6	If No, provide reason for not prescribing aldosterone antagonists	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*
1.7	Was any hydralazine taken?	○ No *(N)* ○ Yes *(Y)*
1.8	If No, provide reason for not prescribing hydralazine	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*
1.9	Were any diuretics taken?	○ No *(N)* ○ Yes *(Y)*
1.10	If No, provide reason for not prescribing diuretics	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*

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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?	*Text*
1.2	What was the individual dose of the medication per administration?	*Integer*
1.3	What is the unit of the medication per administration?	○ mcg *(ug)* ○ mg *(mg)* ○ g *(g)* ○ Ml *(mL)* ○ Application *(APPLICATION)* ○ International Unit (IU) *(IU)* ○ Tablet *(TABLET)* ○ Capsule *(CAPSULE)* ○ Other *(OTHER)*
1.4	What was the frequency of the medication?	○ BD; Twice per day *(BID)* ○ As needed *(PRN)*
1.5	What was the route of administration of the medication?	○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL
1.6	Start Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
1.7	Is the medication ongoing?	○ AFTER ○ BEFORE ○ COINCIDENT ○ DURING ○ DURING/AFTER ○ ONGOING ○ UNKNOWN
1.8	End Date	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?	○ No *(N)* ○ Yes *(Y)*
2.2	If applicable, why was the medication not given at the recommended regimen?	*Text*

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Prior Psoriasis Treatments

Ref	CRF Question	Data Collected
1.1	Has the subject had any psoriasis treatments before the study start?	○ No *(N)* ○ Yes *(Y)*
1.2	What is the subcategory for the treatment?	○ Biologic *(BIOLOGIC)* ○ Non-Biologic *(NON-BIOLOGIC)* ○ Phototherapy *(PHOTOTHERAPY)*
1.3	What was the name of the treatment?	_____ *Text*
1.4	What was the route of administration of the medication?	○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL
1.5	If the treatment was systemic, what was the individual dose?	_____ *Text*
1.6	What is the unit of the medication per administration?	○ mcg *(ug)* ○ mg *(mg)* ○ g *(g)* ○ Ml *(mL)* ○ Application *(APPLICATION)* ○ International Unit (IU) *(IU)* ○ Tablet *(TABLET)* ○ Capsule *(CAPSULE)* ○ Other *(OTHER)*
2.1	If the medication was a biologic, what device was used for drug administration?	○ Single-dose pen *(SINGLE-DOSE PEN)* ○ Multiple-dose pen *(MULTIPLE-DOSE PEN)* ○ Pre-filled syringe *(PRE-FILLED SYRINGE)* ○ Syringe *(SYRINGE)* ○ Not Applicable *(NOT APPLICABLE)*
3.1	Start Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
3.2	Is the medication ongoing?	○ No *(N)* ○ Yes *(Y)*
3.3	End Date	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?	○ Inadequate efficiacy *(INADEQUATE EFFICACY)* ○ Adverse event *(ADVERSE EVENT)* ○ Other-not related to efficacy/adverse event *(OTHER-NOT RELATED TO EFFICACY/ADVERSE EVENTS)*

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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?	○ FACE *(FACE)* ○ GENITALIA *(GENITALIA)* ○ Hand *(HAND)* ○ HEAD *(HEAD)* ○ Lower Extremity *(LIMB, LOWER)* ○ Upper Extremity *(LIMB, UPPER)* ○ SCALP *(SCALP)* ○ Torso *(TRUNK)*
1.2	If applicable, what was the laterality of the anatomical location?	○ LEFT ○ RIGHT ○ NOT APPLICABLE
1.3	If applicable, what was the directionality of the anatomical location?	○ ANTERIOR ○ POSTERIOR ○ NOT APPLICABLE

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Subject eligibility

Ref	CRF Question	Data Collected
1.1	Does the subject meet all inclusion criteria and none of the exclusion criteria?	○ Yes *(Y)* ○ No *(N)*
2.1	Seq. no.	_____ *Integer*
2.2	Inclusion criteria not met *Tick all that apply*	☐ Inclusion 1 *(INCL01)* ☐ Inclusion 2 *(INCL02)* ☐ Inclusion 3 *(INCL03)* ☐ Inclusion 4 *(INCL04)* ☐ Inclusion 5 *(INCL05)* ☐ Inclusion 6 *(INCL06)* ☐ Inclusion 7 *(INCL07)* ☐ Inclusion 8 *(INCL08)* ☐ Inclusion 9 *(INCL09)* ☐ Inclusion 10 *(INCL10)*
3.1	Seq. no.	_____ *Integer*
3.2	Exclusion criteria met *Tick all that apply*	☐ Exclusion 1 *(EXCL01)* ☐ Exclusion 2 *(EXCL02)* ☐ Exclusion 3 *(EXCL03)* ☐ Exclusion 4 *(EXCL04)* ☐ Exclusion 5 *(EXCL05)* ☐ Exclusion 6 *(EXCL06)* ☐ Exclusion 7 *(EXCL07)* ☐ Exclusion 8 *(EXCL08)* ☐ Exclusion 9 *(EXCL09)* ☐ Exclusion 10 *(EXCL10)*

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Adverse Events

Ref	CRF Question	Data Collected
1.1	Were any adverse events experienced?	○ No *(N)* ○ Yes *(Y)*
1.2	AE Group ID	*Text*
1.3	What is the adverse event term?	*Text*
2.1	AE Identifier	*Integer*
2.2	What is the date the adverse event started?	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
2.3	Is the adverse event still ongoing?	*Text*
2.4	End date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
2.5	What is the toxicity grade of the adverse event?	○ Absent *(0)* ○ Mild *(1)* ○ Moderate *(2)* ○ Severe *(3)* ○ Life Threatening *(4)* ○ Fatal *(5)*
2.6	Is the adverse event serious?	○ No *(N)* ○ Yes *(Y)*
2.7	Congenital Anomaly or Birth Defect	☐ No *(N)* ☐ Yes *(Y)*
2.8	Significant Disability	☐ No *(N)* ☐ Yes *(Y)*
2.9	Death	☐ No *(N)* ☐ Yes *(Y)*
2.10	Hospitalization	☐ No *(N)* ☐ Yes *(Y)*
2.11	Life Threatening	☐ No *(N)* ☐ Yes *(Y)*
2.12	Occurs with Overdose	☐ No *(N)* ☐ Yes *(Y)*
2.13	Other Medically Important Event	☐ No *(N)* ☐ Yes *(Y)*
2.14	Concomitant or Additional Treament Given	☐ No *(N)* ☐ Yes *(Y)*
2.15	Is this event related to study treatment?	○ No *(N)* ○ Yes *(Y)*

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Adverse Events

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

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ECG Test Results

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

Death

Ref	CRF Question	Data Collected
1.1	Were any death detail assessments collected?	○ No *(N)* ○ Yes *(Y)*
2.1	Collection Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
3.1	Death Date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
4.1	What is the primary cause of death?	*Text*
4.2	What is the secondary cause of death?	*Text*
4.3	What is the location of death?	○ Home *(HOME)* ○ Hospital *(HOSPITAL)* ○ Nursing/Rehabilitation Home *(NURSING/REHABILITATION HOME)*
4.4	Was the death witnessed?	*Text*

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Adverse Events

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1.1	Were any adverse events experienced?	○ No *(N)* ○ Yes *(Y)*
1.2	AE Group ID	*Text*
1.3	What is the adverse event term?	*Text*
2.1	AE Identifier	*Integer*
2.2	What is the date the adverse event started?	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
2.3	Is the adverse event still ongoing?	*Text*
2.4	End date	DD-MMM-YYYY *Date* *Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
2.5	What is the toxicity grade of the adverse event?	○ Absent *(0)* ○ Mild *(1)* ○ Moderate *(2)* ○ Severe *(3)* ○ Life Threatening *(4)* ○ Fatal *(5)*
2.6	Is the adverse event serious?	○ No *(N)* ○ Yes *(Y)*
2.7	Congenital Anomaly or Birth Defect	☐ No *(N)* ☐ Yes *(Y)*
2.8	Significant Disability	☐ No *(N)* ☐ Yes *(Y)*
2.9	Death	☐ No *(N)* ☐ Yes *(Y)*
2.10	Hospitalization	☐ No *(N)* ☐ Yes *(Y)*
2.11	Life Threatening	☐ No *(N)* ☐ Yes *(Y)*
2.12	Occurs with Overdose	☐ No *(N)* ☐ Yes *(Y)*
2.13	Other Medically Important Event	☐ No *(N)* ☐ Yes *(Y)*
2.14	Concomitant or Additional Treament Given	☐ No *(N)* ☐ Yes *(Y)*
2.15	Is this event related to study treatment?	○ No *(N)* ○ Yes *(Y)*

Adverse Events

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