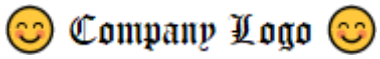
CRF Specification for Test Trial

Selection of CRF forms available at CDISC

Protocol Name: Test CRF

CRF Creation date: 2021-01-12T11:48:44+01:00



Company Name

Table of Contents

Visit Matrix

Visit Number	1	2	
Event/ Form	Screening	Visit 1	Death
Mandatory visit	**Yes**	**Yes**	**Yes**
Background Heart Failure Maintenance Medications Part 1	✓		
Background Heart Failure Maintenance Medications Part 2	✓		
Body Sites of Psoriasis Involvement at Baseline	✓		
Death			✓
Demographics	✓		
ECG Test Results *[∞]*		✓	
Prior Psoriasis Treatments	✓		

Company Name Company Logo	Study/Trial: Test	Subject Number:
	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Background Heart Failure Maintenance Medications Part 1

CRF instructions: *Indicate whether the listed class/type of background heart failure medication was prescribed to the subject (see the study protocol for details).*

Indicate if any ARBs were taken. If Yes, include the appropriate information in Part 2.	1.1	Were any angiotensin-converting enzyme (ACE) inhibitors taken?	○ N ○ Y
Indicate the reason ACE inhibitors were not prescribed. If the reason is unknown, select "Unknown."	1.2	If No, provide reason for not prescribing ARBs.	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*
Indicate if any ARNIs were taken. If Yes, include the appropriate information in Part 2.	1.3	Were any angiotensin receptor/neprilysin inhibitors (ARNIs) taken?	○ N ○ Y
Indicate the reason ARNIs were not prescribed. If the reason is unknown, select "Unknown."	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)*
Indicate if any aldosterone antagonists were taken. If Yes, include the appropriate information in Part 2.	1.5	Were any aldosterone antagonists taken?	○ N ○ Y
Indicate the reason aldosterone antagonists were not prescribed. If the reason is unknown, select "Unknown."	1.6	If No, provide reason for not prescribing aldosterone antagonists.	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*
Indicate if any hydralazine was taken. If Yes, include the appropriate information in Part 2.	1.7	Was any hydralazine taken?	○ N ○ Y
Indicate the reason hydralazine was not prescribed. If the reason is unknown, select "Unknown."	1.8	If No, provide reason for not prescribing hydralazine.	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*
Indicate if any diuretics were taken. If Yes, include the appropriate information in Part 2.	1.9	Were any diuretics taken?	○ N ○ Y

Company Name Company Logo	Study/Trial: Test	Subject Number:
	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Background Heart Failure Maintenance Medications Part 1

CRF instructions: *Indicate whether the listed class/type of background heart failure medication was prescribed to the subject (see the study protocol for details).*

Indicate the reason diuretics were not prescribed. If the reason is unknown, select "Unknown."	1.10	If No, provide reason for not prescribing diuretics.	○ Contraindication *(CONTRAINDICATION)* ○ Treatment not indicated *(TREATMENT NOT INDICATED)* ○ Cost *(COST)* ○ Unknown *(UNKNOWN)*

Company Name	Study/Trial: Test	Subject Number:
Company Logo	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Background Heart Failure Maintenance Medications Part 2

CRF instructions: *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.*

Record only 1 medication per line. Provide the full trade or proprietary name of the medication; otherwise, the generic name may be recorded.	1.1	What was the medication name?	
Record the dose of concomitant medication taken per administration (e.g., 200).	1.2	What was the individual dose of the medication per administration?	
Record the dose unit of the dose of concomitant medication taken (e.g., mg).	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)*
Record how often the concomitant medication was taken (e.g., BID, PRN).	1.4	What was the frequency of the medication?	○ BID ○ PRN
Provide the route of administration for the concomitant medication.	1.5	What was the route of administration of the medication?	○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL
Record the date the concomitant medication was first taken, using this format (DD-MON-YYYY).	1.6	Start Date	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
Record the concomitant medication as ongoing or not, to indicate whether the subject has stopped taking the concomitant medication at the time of data collection. If the concomitant medication is ongoing, leave the end date blank.	1.7	Is the medication ongoing?	○ AFTER ○ BEFORE ○ COINCIDENT ○ DURING ○ DURING/AFTER ○ ONGOING ○ UNKNOWN

Company Name	Study/Trial: Test	Subject Number:
Company Logo	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Background Heart Failure Maintenance Medications Part 2

CRF instructions: *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.*

Record the date the concomitant medication was stopped, using this format (DD-MON-YYYY). If the subject has not stopped taking the concomitant medication, leave this field blank.	1.8	End Date	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
Indicate if, in the investigator's opinion, the dose regimen was given at the recommended regimen, according to the heart failure standard-of-care guidelines referenced in the protocol.	2.1	If applicable, was the medication given at the recommended regimen?	○ N ○ Y
Provide the reason why the recommended dose regimen was not administered at the recommended regimen.	2.2	If applicable, why was the medication not given at the recommended regimen?	

Company Name Company Logo	Study/Trial: Test	Subject Number:
	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Body Sites of Psoriasis Involvement at Baseline

CRF instructions: *CRF Instructions: Use one page per affected area.*

Record the body location which has plaque psoriasis involvement.	1.1	What was the location of psoriasis lesion involvement?	○ FACE ○ GENITALIA ○ HAND ○ HEAD ○ LIMB, LOWER ○ LIMB, UPPER ○ SCALP ○ TRUNK
Specify the laterality of the lesion.	1.2	If applicable, what was the laterality of the anatomical location?	○ LEFT ○ RIGHT ○ NOT APPLICABLE
Specify the directionality of the lesion.	1.3	If applicable, what was the directionality of the anatomical location?	○ ANTERIOR ○ POSTERIOR ○ NOT APPLICABLE

Company Name Company Logo	Study/Trial: Test	Subject Number:
	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Death

Indicate if the death details are known. If Yes, include the appropriate details where indicated on the CRF.	1.1	Were any death detail assessments collected?	○ N ○ Y
Record the date of collection using this format (DD-MON-YYYY).	1.2	Collection Date	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
Record the date of death.	2.1	Death Date	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
Record the primary cause of death.	3.1	What is the primary cause of death?	
Record the secondary cause of death, if applicable.	3.2	What is the secondary cause of death?	
Record the physical location where the subject died.	3.3	What is the location of death?	○ Home *(HOME)* ○ Hospital *(HOSPITAL)* ○ Nursing/Rehabilitation Home *(NURSING/REHABILITATION HOME)*
Indicate if the death was witnessed, using NY codelist format.	3.4	Was the death witnessed?	

Company Name Company Logo	Study/Trial: Test	Subject Number:
	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Demographics

Partial dates are allowed.	1.1	Birth Date	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
Sex	1.2		○ F ○ M ○ U ○ UNDIFFERENTIATED
Ethnic	1.3	Ethnicity	○ HISPANIC OR LATINO ○ NOT HISPANIC OR LATINO ○ NOT REPORTED ○ UNKNOWN
Race	1.4	Race	○ AMERICAN INDIAN OR ALASKA NATIVE ○ ASIAN ○ BLACK OR AFRICAN AMERICAN ○ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER ○ NOT REPORTED ○ UNKNOWN ○ WHITE

Company Name Company Logo	Study/Trial: Test	Subject Number:
	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

ECG Test Results [Repeating form]

1.1	Was the ECG performed?	○ N ○ Y
1.2	What was the ECG date?	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
1.3	What was the ECG time?	--:-- -- *The displayed time is formatted based on the locale of the user's browser. Always store times as ISO8601 in SDTM.*
1.4	What was the result of the ECG?	○ Normal *(NORMAL)* ○ Abnormal *(ABNORMAL)*
2.1	Was the ECG clinically significant?	○ N ○ Y

Company Name	Study/Trial: Test	Subject Number:
Company Logo	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Prior Psoriasis Treatments

Indicate if the subject had any prior psoriasis treatments. If Yes, include the appropriate details where indicated on the CRF.	1.1	Has the subject had any psoriasis treatments before the study start?	○ N ○ Y
Record the treatment subcategory.	1.2	What is the subcategory for the treatment?	○ Biologic *(BIOLOGIC)* ○ Non-Biologic *(NON-BIOLOGIC)* ○ Phototherapy *(PHOTOTHERAPY)*
Record only 1 treatment per line. Provide the full trade or proprietary name of the; otherwise, the generic name may be recorded.	1.3	What was the name of the treatment?	
Provide the route of administration for the concomitant medication.	1.4	What was the route of administration of the medication?	○ ORAL ○ SUBCUTANEOUS ○ TOPICAL ○ TRANSDERMAL
Record the dose of medication per administration (e.g., 200).	1.5	If the treatment was systemic, what was the individual dose?	
Record the dose unit of the dose of concomitant medication taken (e.g., mg).	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)*
Record the device that was used for drug administration.	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)*
Record the date the treatment was first started using this format (DD-MON-YYYY). If the subject has been taking the medication for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Prior treatments that are exclusionary should have both a start date and an end date.	3.1	Start Date	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*

Company Name	Study/Trial: Test	Subject Number:
Company Logo	Site Number:	Subject Initials:
Protocol: Test CRF	Investigator:	Visit:

Prior Psoriasis Treatments

Record the treatment as ongoing if the subject has not stopped the treatment or medication at the time of data collection; the end date should be left blank.	3.2	Is the medication ongoing?	○ N ○ Y
Record the date the concomitant medication was stopped, using this format (DD-MON-YYYY). If the subject has not stopped taking the concomitant medication, leave this field blank.	3.3	End Date	mm/dd/yyyy *The displayed date is formatted based on the locale of the user's browser. Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.*
Record the primary reason the treatment was discontinued.	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)*