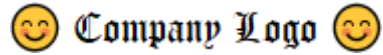


CRF Specification for Test Trial

Selection of CRF forms available at CDISC

Protocol Name: Test CRF

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



Company Name

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Visit Matrix



Visit Number	1	2		TV.VISITNUM
Event/ Form	Screening	Visit 1	Death	TV.VISIT
Mandatory visit	Yes	Yes	Yes	NOT SUBMITTED
Background Heart Failure Maintenance Medications Part 1	✓			NOT SUBMITTED
Background Heart Failure Maintenance Medications Part 2	✓			NOT SUBMITTED
Body Sites of Psoriasis Involvement at Baseline	✓			NOT SUBMITTED
Death			✓	NOT SUBMITTED
Demographics	✓			NOT SUBMITTED
ECG Test Results [∞]		✓		NOT SUBMITTED
Prior Psoriasis Treatments	✓			NOT SUBMITTED

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/> DM.STUDYID	Subject Number: <input type="text"/> DM.SUBJID
	Site Number: <input type="text"/> DM.SITEID	Subject Initials: <input type="text"/> NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/> NOT SUBMITTED	Visit: <input type="text"/> SV.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?	<input type="radio"/> N <input type="radio"/> Y	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARBs'
	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)	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARBs'
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?	<input type="radio"/> N <input type="radio"/> Y	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs'
	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)	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='ARNIs'
Indicate if any aldosterone antagonists were taken. If Yes, include the appropriate information in Part 2.	1.5	Were any aldosterone antagonists taken?	<input type="radio"/> N <input type="radio"/> Y	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Aldosterone Antagonists'

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/> DM.STUDYID	Subject Number: <input type="text"/> DM.SUBJID
	Site Number: <input type="text"/> DM.SITEID	Subject Initials: <input type="text"/> NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/> NOT SUBMITTED	Visit: <input type="text"/> SV.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 aldosterone antagonists were not prescribed. If the reason is unknown, select "Unknown."	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)	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Aldosterone Antagonists'
Indicate if any hydralazine was taken. If Yes, include the appropriate information in Part 2.	1.7	Was any hydralazine taken?	<input type="radio"/> N <input type="radio"/> Y	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Hydralazine'
Indicate the reason hydralazine was not prescribed. If the reason is unknown, select "Unknown."	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)	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Hydralazine'
Indicate if any diuretics were taken. If Yes, include the appropriate information in Part 2.	1.9	Were any diuretics taken?	<input type="radio"/> N <input type="radio"/> Y	CM.CMOCCUR, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Diuretics'
Indicate the reason diuretics were not prescribed. If the reason is unknown, select "Unknown."	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)	CM.CMREASND, CMCAT='Heart Failure Maintenance Medication', CMPRESP='Y', CMTRT='Diuretics'

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/> DM.STUDYID	Subject Number: <input type="text"/> DM.SUBJID
	Site Number: <input type="text"/> DM.SITEID	Subject Initials: <input type="text"/> NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/> NOT SUBMITTED	Visit: <input type="text"/> SV.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.


Record the dose of concomitant medication taken per administration (e.g., 200).



Record the dose unit of the dose of concomitant medication taken (e.g., mg).

Record how often the concomitant medication was taken (e.g., BID, PRN).

Provide the route of administration for the concomitant medication.

Record the date the concomitant medication was first taken, using this format (DD-MON-YYYY).

1.1	What was the medication name?	<input type="text"/>	CM.CMTRT
1.2	What was the individual dose of the medication per administration?	<input type="text"/>	CM.CMDOSE
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)	CM.CMDOSU, CMCAT='ANTIPSORIATIC'
1.4	What was the frequency of the medication?	<input type="radio"/> BID <input type="radio"/> PRN	CM.CMDOSFRQ
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	CM.CMROUTE, CMCAT='ANTIPSORIATIC'
1.6	Start Date	<input type="text" value="mm/dd/yyyy"/>  The displayed date is formatted based on the locale of the user's browser	CM.CMSTDTC

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/> DM.STUDYID	Subject Number: <input type="text"/> DM.SUBJID
	Site Number: <input type="text"/> DM.SITEID	Subject Initials: <input type="text"/> NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/> NOT SUBMITTED	Visit: <input type="text"/> SV.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 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.

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.

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.

Provide the reason why the recommended dose regimen was not administered at the recommended regimen.



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	CM.CMENRTPT CM.CMENDTC, CMCAT='ANTIPSORIATIC' SUPPCM.QVAL, SUPPCM.QNAM='CMRRGYN', SUPPCM.QLABEL='Was the medication given at the recommended regimen' SUPPCM.QVAL, SUPPCM.QVAL='CMRRGREA', SUPPCM.QLABEL='why was the medication not given at the recommended regimen'
1.8	End Date	<input type="text" value="mm/dd/yyyy"/>  The displayed date is formatted based on the locale of the user's browser	
2.1	If applicable, was the medication given at the recommended regimen?	<input type="radio"/> N <input type="radio"/> Y	
2.2	If applicable, why was the medication not given at the recommended regimen?	<input type="text"/>	

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/>	DM.STUDYID	Subject Number: <input type="text"/>	DM.SUBJID
	Site Number: <input type="text"/>	DM.SITEID	Subject Initials: <input type="text"/>	NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/>	NOT SUBMITTED	Visit: <input type="text"/>	SV.VISIT

Body Sites of Psoriasis Involvement at Baseline

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

<p><i>Record the body location which has plaque psoriasis involvement.</i></p>	1.1	What was the location of psoriasis lesion involvement?	<input type="radio"/> FACE <input type="radio"/> GENITALIA <input type="radio"/> HAND <input type="radio"/> HEAD <input type="radio"/> LIMB, LOWER <input type="radio"/> LIMB, UPPER <input type="radio"/> SCALP <input type="radio"/> TRUNK	TU.TULOC, TUTESTCD='LESIDENT', TUTEST='Lesion Identification'	
	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		TU.TULAT, TUTESTCD='LESIDENT', TUTEST='Lesion Identification'
	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		

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/>	DM.STUDYID	Subject Number: <input type="text"/>	DM.SUBJID
	Site Number: <input type="text"/>	DM.SITEID	Subject Initials: <input type="text"/>	NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/>	NOT SUBMITTED	Visit: <input type="text"/>	SV.VISIT

Death

Indicate if the death details are known. If Yes, include the appropriate details where indicated on the CRF.

Record the date of collection using this format (DD-MON-YYYY).



Record the date of death.



Record the primary cause of death.

Record the secondary cause of death, if applicable.


Record the physical location where the subject died.



Indicate if the death was witnessed, using NY codelist format.

1.1	Were any death detail assessments collected?	<input type="radio"/> N <input type="radio"/> Y	NOT SUBMITTED
1.2	Collection Date	<input type="text" value="mm/dd/yyyy"/>  <i>The displayed date is formatted based on the locale of the user's browser</i>	DD.DDDTC
2.1	Death Date	<input type="text" value="mm/dd/yyyy"/>  <i>The displayed date is formatted based on the locale of the user's browser</i>	DM.DTHDTC
3.1	What is the primary cause of death?	<input type="text"/>	DD.DDORRES, DDTESTCD='DIAGPRIM', DDTEST='Primary Diagnosis'
3.2	What is the secondary cause of death?	<input type="text"/>	DD.DDORRES, DDTESTCD='DIAGSEC', DDTEST='Secondary Diagnosis'
3.3	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)	DD.DDORRES, DDTESTCD='LOCOTH', DDTEST='What is the location of death'
3.4	Was the death witnessed?	<input type="text"/>	DD.DDORRES, DDTESTCD='DTHWIT', DDTEST='Was Death Witnessed'



Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/>	DM.STUDYID	Subject Number: <input type="text"/>	DM.SUBJID
	Site Number: <input type="text"/>	DM.SITEID	Subject Initials: <input type="text"/>	NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/>	NOT SUBMITTED	Visit: <input type="text"/>	SV.VISIT



Demographics

<i>Partial dates are allowed.</i>	1.1	Birth Date	<input type="text" value="mm/dd/yyyy"/>  <i>The displayed date is formatted based on the locale of the user's browser</i>	DM.BRTHDTC, Partial dates are to be recorded according to ISO 8601.
Sex	1.2		<input type="radio"/> F <input type="radio"/> M <input type="radio"/> U <input type="radio"/> UNDIFFERENTIATED	DM.SEX
Ethnic	1.3	Ethnicity	<input type="radio"/> HISPANIC OR LATINO <input type="radio"/> NOT HISPANIC OR LATINO <input type="radio"/> NOT REPORTED <input type="radio"/> UNKNOWN	DM.ETHNIC
Race	1.4	Race	<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	DM.RACE

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/>	DM.STUDYID	Subject Number: <input type="text"/>	DM.SUBJID
	Site Number: <input type="text"/>	DM.SITEID	Subject Initials: <input type="text"/>	NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/>	NOT SUBMITTED	Visit: <input type="text"/>	SV.VISIT

ECG Test Results [Repeating form]

1.1	Was the ECG performed?	<input type="radio"/> N <input type="radio"/> Y	NOT SUBMITTED
1.2	What was the ECG date?	<input type="text" value="mm/dd/yyyy"/>  <i>The displayed date is formatted based on the locale of the user's browser</i>	EG.EGSTDTC, Date and time are to be combined into one variable according to ISO 8601
1.3	What was the ECG time?	<input type="text" value="--:-- --"/>  <i>The displayed time is formatted based on the locale of the user's browser</i>	EG.EGSTDTC, Date and time are to be combined into one variable according to ISO 8601
1.4	What was the result of the ECG?	<input type="radio"/> Normal (NORMAL) <input type="radio"/> Abnormal (ABNORMAL)	EG.EGORRES
2.1	Was the ECG clinically significant?	<input type="radio"/> N <input type="radio"/> Y	SUPPEG.QVAL, SUPPEG.QNAM='EGCLSIG', SUPPEG.QLABEL='ECG clinically significant'

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/>	DM.STUDYID	Subject Number: <input type="text"/>	DM.SUBJID
	Site Number: <input type="text"/>	DM.SITEID	Subject Initials: <input type="text"/>	NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/>	NOT SUBMITTED	Visit: <input type="text"/>	SV.VISIT

Prior Psoriasis Treatments

Indicate if the subject had any prior psoriasis treatments. If Yes, include the appropriate details where indicated on the CRF.

Record the treatment subcategory.

Record only 1 treatment per line. Provide the full trade or proprietary name of the; otherwise, the generic name may be recorded.



Provide the route of administration for the concomitant medication.

Record the dose of medication per administration (e.g., 200).

Record the dose unit of the dose of concomitant medication taken (e.g., mg).

Record the device that was used for drug administration.

1.1	Has the subject had any psoriasis treatments before the study start?	<input type="radio"/> N <input type="radio"/> Y	CM.CMOCCUR, CMCAT='ANTIPSORIATIC', CMTRT='ANTIPSORIATIC', CMPRESP='Y', CMSTRF='BEFORE'
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)	CM.CMSCAT, CMCAT='ANTIPSORIATIC'
1.3	What was the name of the treatment?	<input type="text"/>	CM.CMTRT, CMCAT='ANTIPSORIATIC'
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	CM.CMROUTE, CMCAT='ANTIPSORIATIC'
1.5	If the treatment was systemic, what was the individual dose?	<input type="text"/>	CM.CMDOSTXT, CMCAT='ANTIPSORIATIC', CMDOSE if all values of CMDOSTXT are numeric
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)	CM.CMDOSU, CMCAT='ANTIPSORIATIC'
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)	SUPPCM.QVAL, SUPPCM.QNAM='SPDEVID', SUPPCM.QLABEL='Device Identifier'

Company Name  Company Logo 	Study/Trial: <input type="text" value="Test"/>	DM.STUDYID	Subject Number: <input type="text"/>	DM.SUBJID
	Site Number: <input type="text"/>	DM.SITEID	Subject Initials: <input type="text"/>	NOT SUBMITTED
Protocol: Test CRF	Investigator: <input type="text"/>	NOT SUBMITTED	Visit: <input type="text"/>	SV.VISIT



Prior Psoriasis Treatments

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.

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.

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.

Record the primary reason the treatment was discontinued.

3.1	Start Date	<input type="text" value="mm/dd/yyyy"/>  <i>The displayed date is formatted based on the locale of the user's browser</i>	CM.CMSTDTC, CMCAT='ANTIPSORIATIC' CM.CMENRTPT, CMCAT='ANTIPSORIATIC', If Yes, CMENRTPT='ONGOING'. If No, CMENRF=blank CM.CMENDTC, CMCAT='ANTIPSORIATIC' SUPPCM.QVAL, SUPPCM.QNAM='CMRSDISC', SUPPCM.QLABEL='Reason for treatment discontinuation'
3.2	Is the medication ongoing?	<input type="radio"/> N <input type="radio"/> Y	
3.3	End Date	<input type="text" value="mm/dd/yyyy"/>  <i>The displayed date is formatted based on the locale of the user's browser</i>	
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)	