

CRF Book

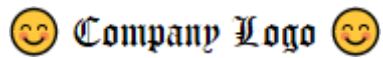
CRF Specification for Test Trial

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			✓

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Screening

Demographics


Ref	CRF Question	Data Collected
1.1		<input type="text" value="DD-MMM-YYYY"/> <i>Date</i> <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
1.2		<input type="radio"/> Female (F) <input type="radio"/> Male (M) <input type="radio"/> U; UNK; Unknown (U) <input type="radio"/> UNDIFFERENTIATED (UNDIFFERENTIATED)
1.3		<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)
1.4		<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

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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		<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)

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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		<input type="text"/> Text
1.2		<input type="text"/> Integer
1.3		<input type="radio"/> mcg (<i>ug</i>) <input type="radio"/> mg (<i>mg</i>) <input type="radio"/> g (<i>g</i>) <input type="radio"/> mL (<i>mL</i>) <input type="radio"/> Application (<i>APPLICATION</i>) <input type="radio"/> International Unit (IU) (<i>IU</i>) <input type="radio"/> Tablet (<i>TABLET</i>) <input type="radio"/> Capsule (<i>CAPSULE</i>) <input type="radio"/> Other (<i>OTHER</i>)
1.4		<input type="radio"/> BD; Twice per day (<i>BID</i>) <input type="radio"/> As needed (<i>PRN</i>)
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 <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
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 <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
2.1		<input type="radio"/> No (<i>N</i>) <input type="radio"/> Yes (<i>Y</i>)
2.2		<input type="text"/> Text

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Screening


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.

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Screening

Prior Psoriasis Treatments

Ref	CRF Question	Data Collected
4.1		<div><input type="radio"/> Inadequate efficiacy (<i>INADEQUATE EFFICACY</i>)</div> <div><input type="radio"/> Adverse event (<i>ADVERSE EVENT</i>)</div> <div><input type="radio"/> Other-not related to efficacy/adverse event (<i>OTHER-NOT RELATED TO EFFICACY/ADVERSE EVENTS</i>)</div>

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Screening

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

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Visit 1

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)

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Visit 1


Adverse Events

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

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Visit 1


ECG Test Results

Ref	CRF Question	Data Collected
1.1		<input type="radio"/> No (N) <input type="radio"/> Yes (Y)
1.2		<input type="text" value="DD-MMM-YYYY"/> <i>Date</i> <i>Always collect dates as DD-MMM-YYYY and store dates as ISO8601 in SDTM.</i>
1.3		<input type="text" value="HH:MM"/> <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)

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Death



Death

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

 Company Logo 	Your Company	Test Trial	
	Site <input type="text"/>	Subject identifier <input type="text"/>	Death <input type="text"/>

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"/> 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"/> 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)

		<input type="radio"/> Yes (Y)	
 Company Logo 		Your Company	Test Trial
		Site <input type="text"/>	Subject identifier <input type="text"/>
		Death <input type="text"/>	

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>)

