CRF Specification for Test Trial abcd

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Protocol Name: Test Trial

CRF Creation date: 2020-05-07T12:44:01+02:00

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AE/CM/CP/Other events involving IMP Events ***Design note: This form is only used in adolescent trials, where a subject might reach a country specific legal age that require them to sign an informed consent during the conduct of the trial.***			**SDTM Annotation**
1.1	Did the subject have any adverse events since screening	○ Yes ○ No	NOT SUBMITTED
1.2	Did the subject take any concomitant medications?	○ Yes ○ No	NOT SUBMITTED
1.3	Did the subject have any concurrent procedures/surgeries since screening?	○ Yes ○ No	NOT SUBMITTED
1.4	Did the subject have any other events involving IMP since screening? *Internal note: If the code Lack of efficacy is added to the item 'other event involving IMP' on the form 'other event involving IMP' then adjust the CRF guidance text accordingly*	○ Yes ○ No	

Demographics			SDTM Annotation
1.1	Date of birth	mm/dd/yyyy	BRTHDTC
2.1	Age		QVAL, SUPPDM.QNAM=AGEn. Set SUPPDM.QNAM=AGEnVIS where QVAL=the visit where age is collected
2.2	Age unit	○ Year(s)	QVAL, SUPPDM.QNAM=AGEnU n is a consequitive counter starting from 1
3.1	Sex	○ Male ○ Female	SEX
3.2	Ethnicity	○ Hispanic or Latino ○ Not Hispanic or Latino	ETHNIC
3.3	Race	○ White ○ Black or African American ○ Asian ○ American Indian or Alaska Native ○ Native Hawaiian or Other Pacific Islander ○ Other	RACE, if RACE=OTHER then value is set to NULL
3.4	Race	○ White ○ Black or African American ○ Asian Japanese ○ Asian Other ○ American Indian or Alaska Native ○ Native Hawaiian or Other Pacific Islander ○ Other	RACE, if RACE=OTHER then value is set to NULL. If one of the two Asian races are indicated, set RACE=ASIAN and store original value in SUPPDM.QNAM=RACEC
4.1	[If Other,]Specify		QVAL, SUPPDM.QNAM=RACEOTH

Height and weight			SDTM Annotation
1.1	Height		VSORRES, VSTESTCD=HEIGHT
1.2	Unit height	○ cm ○ in	VSORRESU, VSTESTCD=HEIGHT
1.3	Weight		VSORRES, VSTESTCD=WEIGHT
1.4	Unit weight	○ kg ○ lb	VSORRESU, VSTESTCD=WEIGHT
1.5	Body Mass Index (BMI)		VSORRES, VSTESTCD=BMI
1.6	BMI unit	○ kg/m2	VSORRESU, VSTESTCD=BMI

Urine pregnancy test			SDTM Annotation
1.1	Is the female of child-bearing potential?	○ Yes ○ No	RPORRES, RPTESTCD=CHILDPOT
1.2	[If Yes,]Was a urine pregnancy test performed?	○ Yes ○ No	RPORRES, RPTESTCD=HCGDONE. If No then PRSTAT=NOT DONE
1.3	[If No,]Specify reason		RPREASND
2.1	[If Yes,]Urine pregnancy test date	mm/dd/yyyy	LBDTC, LBCAT=URINALYSIS, LBTESTCD=HCG, LBSPEC=URINE, LBSPID=COLLECTED
2.2	[If Yes,]Result	○ Positive ○ Negative	LBORRES, LBCAT=URINALYSIS, LBTESTCD=HCG, LBSPEC=URINE, LBSPID=COLLECTED

Adverse event			SDTM Annotation
1.1	AE identifier		AESPID
2.1	Adverse event		AETERM
3.1	Location of AE relative to treatment area	○ Non-cutaneous ○ Lesional/perilesional ○ Distant ○ Inside treatment area ○ Outside treatment area ○ Application area	QVAL, SUPPAE.QNAM=AERELTRT
4.1	Location of AE	○ NA (Non-cutaneous) ○ Back ○ Scalp ○ Face ○ Chest ○ Arm ○ Leg ○ Trunk ○ Limb ○ Site 1 ○ Site 2 ○ Site 3 ○ Site 4	AELOC, If value does not exist on LOC codelist then place in SUPPAE.QVAL where QNAM=ALTLOC.
4.2	Start date	mm/dd/yyyy	AESTDTC
5.1	If the adverse event started on the SAME DAY a dose was administered, did the adverse event start before or after dosing of IMP?	○ Before dosing ○ After dosing ○ Not applicable	QVAL, SUPPAE.QNAM=AEOCCUR

Adverse event			SDTM Annotation
5.2	Did the adverse event start before the first administration of IMP? *Internal note: Used in e.g. AK trials and Test drug trials. Only one of the questions 'If the adverse event started on the SAME DAY a dose was administered, did the adverse event start before or after dosing of IMP?' or 'Did the adverse event start before the first administration of IMP?' is used. (tralokinumab/placebo) only to be added to question in trials where additional IMP's than the randomized treatment are included. Align the text in the brackets to the protocol. CRF Guidance text: Note the first administration = the administration at week 0/Visit 3. Adjust CRF Guidance to protocol.*	○ Yes ○ No	QVAL, SUPPAE.QNAM=AETRTEM
5.3	Did the adverse event start before the administration of the vaccines?	○ Yes ○ No	QVAL, SUPPAE.QNAM=AEOCCUR
6.1	Stop date *Design note: Day can be unknown but month and year must be filled out*	mm/dd/yyyy	AEENDTC
6.2	Ongoing	○ Yes ○ No	AEENRTPT, If ONGOING then AEENTPT=END OF TRIAL
6.3	Severity	○ Mild ○ Moderate ○ Severe	AESEV
6.4	Was the AE related to IMP?	○ Probably related ○ Possibly related ○ Not related	AEREL
6.5	Action taken with IMP	○ Dose not changed ○ Dose reduced ○ Dose increased ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Unknown	AEACN

Adverse event			SDTM Annotation
6.6	Was the AE related to AxMP (TCS)?	○ Probably related ○ Possibly related ○ Not related	AERELNST
7.1	Was the AE related to IMP (Tdap vaccine)?	○ Probably related ○ Possibly related ○ Not related	QVAL, SUPPAE.QNAM=RELTDAP
7.2	Was the AE related to IMP (meningococcal vaccine)? *Internal note: Item only to be added in trials where additional IMP's than the randomized treatment are included. Align the text in the brackets to the protocol.*	○ Probably related ○ Possibly related ○ Not related	QVAL, SUPPAE.QNAM=RELMENI
8.1	Did the AE start at the same day as CYP cocktail was given?	○ Yes ○ No	QVAL, SUPPAE.QNAM=CYPTRTEM
8.2	[if Yes,]Start time of AE	--:-- --	QVAL, SUPPAE.QNAM=AESTDTC
8.3	[If Yes,]Stop time of AE	--:-- --	QVAL, SUPPAE.QNAM=AEENDTC
9.1	Action taken with AxMP (TCS)	○ Dose not changed ○ Dose reduced ○ Dose increased ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Unknown	QVAL, SUPPAE.QNAM=AEACNNST
10.1	Other action taken (tick all that apply)	☐ None ☐ Concomitant medication ☐ Concurrent procedure	AEACNOTH, IF MULTIPLE ANSWERS ARE GIVEN SET AEACNOTH TO MULTIPLE AND STORE INDIVIDUAL ANSWERS IN SUPPAE
11.1	Withdrawn from trial due to this AE?	○ Yes ○ No	QVAL, SUPPAE.QNAM=AEAWDR
12.1	Was the AE serious?	○ Yes ○ No	AESER
13.1	SAE criteria (Tick all that apply)	☐ Death ☐ Life-threatening ☐ In-patient hospitalisation/prolongation of existing hospitalisation ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important condition	If ticked, set the relevant variable in AE to Y. If Fatal, set AESDTH. If Life-threatening set AESLIFE. If Hospitalisation set AESHOSP.

Adverse event			SDTM Annotation
14.1	Outcome	○ Fatal ○ Not recovered/not resolved ○ Recovering/resolving ○ Recovered/resolved ○ Recovered/resolved with sequelae ○ Unknown	AEOUT
15.1	Is the event an adverse event of special interest?	○ Yes ○ No	QVAL, SUPPAE.QNAM=AESI

Urine dipstick			SDTM Annotation
1.1	Was a urine sample tested with a dipstick?	○ Yes ○ No	LBORRES, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED, LBMETHOD=DIPSTICK. If No, then LBSTAT=NOT DONE and populate LBREASND. If Yes set LBORRES to Y.
1.2	[If No,]Specify reason		LBREASND, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED, LBMETHOD=DIPSTICK.
1.3	[If Yes,]Result	○ Normal ○ Abnormal	LBORRES, LBCAT=URINALYSIS, LBTESTCD=INTP, LBSPEC=URINE, LBSPID=COLLECTED, LBMETHOD=DIPSTICK.

Concomitant medication			SDTM Annotation
1.1	CM Number		CMSPID
1.2	Medication or therapy (generic or brand name)		CMTRT
2.1	Is this medication or therapy a rescue medication for chronic hand eczema?	○ Yes ○ No	QVAL, SUPPCM.QNAM=RESCMED
3.1	Indication		CMINDC
3.2	Dose per administration		CMDOSTXT, If CMDOSTXT is a numeric value, then transfer the number to the numeric field CMDOSE, and set CMDOSTXT to null
3.3	Unit	○ mcg ○ mg ○ g ○ Ml ○ Application ○ International Unit (IU) ○ Tablet ○ Capsule ○ Other	CMDOSU
4.1	[If Other,]Specify		QVAL, SUPPCM.QNAM = DOSUOTH
5.1	Frequency	○ As needed (PRN) ○ Daily (QD) ○ Twice daily (BID) ○ Three times per day (TID) ○ Four times per day ○ Weekly (QS) ○ Monthly (QM) ○ Once ○ Other	CMDOSFRQ
6.1	[If Other,]Specify		QVAL, SUPPCM.QNAM = FRQOTH
7.1	Route	○ Oral ○ Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○ Intramuscular ○ Respiratory (inhalation) ○ Intralesional ○ Intraperitoneal ○ Nasal ○ Vaginal ○ Rectal ○ Intravenous ○ Other	CMROUTE

Concomitant medication			SDTM Annotation
8.1	[If Topical,]Dose form	○ Cream ○ Lotion ○ Ointment ○ Other	CMDOSFRM
9.1	[If Other,]Specify		QVAL, SUPPCM.QNAM=FRMOTH
10.1	Start date	mm/dd/yyyy	CMSTDTC
10.2	Stop date	mm/dd/yyyy	CMENDTC
10.3	Ongoing	○ Yes ○ No	CMENRTPT, CMENTPT=END OF TRIAL

Blood biomarkers			SDTM Annotation
1.1	Did the subject sign the additional informed consent for biomarkers?	○ Yes ○ No	DSDECOD, DSCAT=PROTOCOL MILESTONE. If No then create no record. If Yes then DSTERM=INFORMED CONSENT FOR ADDITIONAL BIOMARKERS, DSDECOD=INFORMED CONSENT OBTAINED
1.2	[If Yes,]Provide date the consent was signed	mm/dd/yyyy	DSSTDTC
2.1	Was sampling performed for blood biomarkers?	○ Yes ○ No ○ Not applicable	LBORRES, LBCAT=BIOMARKER, LBTESTCD=SAMPLE, LBSPEC=SERUM, LBSPID=COLLECTED. If No, then LBSTAT=NOT DONE, LBORRES and populate LBREASND. If Yes set LBORRES to Y. If NA set LBORRES to NA.
2.2	[If No,]Specify reason		LBREASND, LBCAT=BIOMARKER, LBTESTCD=SAMPLE, LBSPEC=SERUM, LBSPID=COLLECTED.

Concurrent procedures			SDTM Annotation
1.1	Procedure number		PRSPID
1.2	Procedure name (include anatomical area if relevant)		PRTRT
1.3	Procedure name		PRTRT
1.4	Indication		PRINDC
1.5	Start date	mm/dd/yyyy	PRSTDTC
1.6	Stop date	mm/dd/yyyy	PRENDTC
1.7	Ongoing	○ Yes ○ No	PRENRTPT, PRENTPT=END OF TRIAL
1.8	Body location	○ Head ○ Trunk ○ Upper limb ○ Lower limb	PRLOC
2.1	Inside treatment area?	○ Yes ○ No ○ Unknown ○ Not applicable	QVAL, SUPPPR.QNAM=INTRTAR

Central laboratory			SDTM Annotation
1.1	Was blood sampling performed?	○ Yes ○ No	LBORRES, LBCAT=BLOOD ANALYSIS, LBTESTCD=SAMPLE, LBSPEC=BLOOD, LBSPID=COLLECTED. If No, then LBSTAT=NOT DONE and populate LBREASND. If Yes set LBORRES to Y.
1.2	[If No,]Specify reason		LBREASND, LBCAT=BLOOD ANALYSIS, LBTESTCD=SAMPLE, LBSPEC=BLOOD, LBSPID=COLLECTED.
1.3	[If Yes,]Date of sampling	mm/dd/yyyy	LBDTC, LBCAT=BLOOD ANALYSIS, LBTESTCD=SAMPLE, LBSPEC=BLOOD, LBSPID=COLLECTED.
1.4	[If Yes,]Time of sampling	--:-- --	LBDTC, LBCAT=BLOOD ANALYSIS, LBTESTCD=SAMPLE, LBSPEC=BLOOD, LBSPID=COLLECTED.
1.5	[If Yes,]Result	○ Normal ○ Abnormal, not clinically significant ○ Abnormal, clinically significant	LBORRES, LBCAT=BLOOD ANALYSIS, LBTESTCD=INTP, LBSPEC=BLOOD, LBSPID=COLLECTED. If Normal LBORRES=NORMAL, if Abnormal LBORRES=ABNORMAL.
1.6	Was a urine sample sent for urinalysis?	○ Yes ○ No ○ Not applicable	LBORRES, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED. If No, then LBSTAT=NOT DONE, LBORRES set as blank and populate LBREASND. If Yes set LBORRES to Y.
1.7	[If No,]Specify reason		LBREASND, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED.
1.8	[If Yes,]Date of sampling	mm/dd/yyyy	LBDTC, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED.
1.9	[If Yes,]Time of sampling	--:-- --	LBDTC, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED.

Central laboratory			SDTM Annotation
1.10	[If Yes,]Result	○ Normal ○ Abnormal, not clinically significant ○ Abnormal, clinically significant	LBORRES, If Clinically Significant SUPPLB.QVAL=Y(QNAM=LBCLSIG),if Not Clinically significant SUPPLB.QVAL=N(QNAM=LBCLSIG)

ECG			SDTM Annotation
1.1	Was the ECG performed?	○ Yes ○ No	EGORRES, EGTESTCD=INTP. If Yes then use EGORRES for the result. If No then EGSTAT=NOT DONE and populate EGREASND.
1.2	[If No,]Specify reason		EGREASND, EGTESTCD=INTP
1.3	Date of ECG	mm/dd/yyyy	EGDTC, EGTESTCD=INTP
1.4	[If Yes,]Results	○ Normal ○ Abnormal, not clinically significant ○ Abnormal, clinically significant	EGORRES, EGTESTCD=INTP. If Normal EGORRES= NORMAL, if Abnormal EGORRES= ABNORMAL. If Clinically Significant SUPPEG.QVAL=Y(QNAM=EGCLSIG), if Not Clinically significant SUPPEG.QVAL=N(QNAM=EGCLSIG)