CRF Specification for Test Trial abcd

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Protocol Name: Test Trial

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

Table of Contents

AE/CM/CP/Other events involving IMP Events

Demographics

Height and weight

Urine pregnancy test

Adverse event

Urine dipstick

Concomitant medication

Blood biomarkers

Concurrent procedures

Central laboratory

ECG

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.***		
1.1	Did the subject have any adverse events since screening	○ Yes ○ No
1.2	Did the subject take any concomitant medications?	○ Yes ○ No
1.3	Did the subject have any concurrent procedures/surgeries since screening?	○ Yes ○ No
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		
1.1	Date of birth	mm/dd/yyyy
2.1	Age	
2.2	Age unit	○ Year(s)
3.1	Sex	○ Male ○ Female
3.2	Ethnicity	○ Hispanic or Latino ○ Not Hispanic or Latino
3.3	Race	○ White ○ Black or African American ○ Asian ○ American Indian or Alaska Native ○ Native Hawaiian or Other Pacific Islander ○ Other
3.4	Race	○ White ○ Black or African American ○ Asian Japanese ○ Asian Other ○ American Indian or Alaska Native ○ Native Hawaiian or Other Pacific Islander ○ Other
4.1	[If Other,]Specify	

Height and weight		
1.1	Height	
1.2	Unit height	○ cm ○ in
1.3	Weight	
1.4	Unit weight	○ kg ○ lb
1.5	Body Mass Index (BMI)	
1.6	BMI unit	○ kg/m2

Urine pregnancy test		
1.1	Is the female of child-bearing potential?	○ Yes ○ No
1.2	[If Yes,]Was a urine pregnancy test performed?	○ Yes ○ No
1.3	[If No,]Specify reason	
2.1	[If Yes,]Urine pregnancy test date	mm/dd/yyyy
2.2	[If Yes,]Result	○ Positive ○ Negative

Adverse event		
1.1	AE identifier	
2.1	Adverse event	
3.1	Location of AE relative to treatment area	○ Non-cutaneous ○ Lesional/perilesional ○ Distant ○ Inside treatment area ○ Outside treatment area ○ Application area
4.1	Location of AE	○ NA (Non-cutaneous) ○ Back ○ Scalp ○ Face ○ Chest ○ Arm ○ Leg ○ Trunk ○ Limb ○ Site 1 ○ Site 2 ○ Site 3 ○ Site 4
4.2	Start date	mm/dd/yyyy
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

Adverse event		
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
5.3	Did the adverse event start before the administration of the vaccines?	○ Yes ○ No
6.1	Stop date *Design note: Day can be unknown but month and year must be filled out*	mm/dd/yyyy
6.2	Ongoing	○ Yes ○ No
6.3	Severity	○ Mild ○ Moderate ○ Severe
6.4	Was the AE related to IMP?	○ Probably related ○ Possibly related ○ Not related
6.5	Action taken with IMP	○ Dose not changed ○ Dose reduced ○ Dose increased ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Unknown

Adverse event		
6.6	Was the AE related to AxMP (TCS)?	○ Probably related ○ Possibly related ○ Not related
7.1	Was the AE related to IMP (Tdap vaccine)?	○ Probably related ○ Possibly related ○ Not related
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
8.1	Did the AE start at the same day as CYP cocktail was given?	○ Yes ○ No
8.2	[if Yes,]Start time of AE	--:-- --
8.3	[If Yes,]Stop time of AE	--:-- --
9.1	Action taken with AxMP (TCS)	○ Dose not changed ○ Dose reduced ○ Dose increased ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Unknown
10.1	Other action taken (tick all that apply)	☐ None ☐ Concomitant medication ☐ Concurrent procedure
11.1	Withdrawn from trial due to this AE?	○ Yes ○ No
12.1	Was the AE serious?	○ Yes ○ No
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

Adverse event		
14.1	Outcome	○ Fatal ○ Not recovered/not resolved ○ Recovering/resolving ○ Recovered/resolved ○ Recovered/resolved with sequelae ○ Unknown
15.1	Is the event an adverse event of special interest?	○ Yes ○ No

Urine dipstick		
1.1	Was a urine sample tested with a dipstick?	○ Yes ○ No
1.2	[If No,]Specify reason	
1.3	[If Yes,]Result	○ Normal ○ Abnormal

Concomitant medication		
1.1	CM Number	
1.2	Medication or therapy (generic or brand name)	
2.1	Is this medication or therapy a rescue medication for chronic hand eczema?	○ Yes ○ No
3.1	Indication	
3.2	Dose per administration	
3.3	Unit	○ mcg ○ mg ○ g ○ Ml ○ Application ○ International Unit (IU) ○ Tablet ○ Capsule ○ Other
4.1	[If Other,]Specify	
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
6.1	[If Other,]Specify	
7.1	Route	○ Oral ○ Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○ Intramuscular ○ Respiratory (inhalation) ○ Intralesional ○ Intraperitoneal ○ Nasal ○ Vaginal ○ Rectal ○ Intravenous ○ Other

Concomitant medication		
8.1	[If Topical,]Dose form	○ Cream ○ Lotion ○ Ointment ○ Other
9.1	[If Other,]Specify	
10.1	Start date	mm/dd/yyyy
10.2	Stop date	mm/dd/yyyy
10.3	Ongoing	○ Yes ○ No

Blood biomarkers		
1.1	Did the subject sign the additional informed consent for biomarkers?	○ Yes ○ No
1.2	[If Yes,]Provide date the consent was signed	mm/dd/yyyy
2.1	Was sampling performed for blood biomarkers?	○ Yes ○ No ○ Not applicable
2.2	[If No,]Specify reason	

Concurrent procedures		
1.1	Procedure number	
1.2	Procedure name (include anatomical area if relevant)	
1.3	Procedure name	
1.4	Indication	
1.5	Start date	mm/dd/yyyy
1.6	Stop date	mm/dd/yyyy
1.7	Ongoing	○ Yes ○ No
1.8	Body location	○ Head ○ Trunk ○ Upper limb ○ Lower limb
2.1	Inside treatment area?	○ Yes ○ No ○ Unknown ○ Not applicable

Central laboratory		
1.1	Was blood sampling performed?	○ Yes ○ No
1.2	[If No,]Specify reason	
1.3	[If Yes,]Date of sampling	mm/dd/yyyy
1.4	[If Yes,]Time of sampling	--:-- --
1.5	[If Yes,]Result	○ Normal ○ Abnormal, not clinically significant ○ Abnormal, clinically significant
1.6	Was a urine sample sent for urinalysis?	○ Yes ○ No ○ Not applicable
1.7	[If No,]Specify reason	
1.8	[If Yes,]Date of sampling	mm/dd/yyyy
1.9	[If Yes,]Time of sampling	--:-- --

Central laboratory		
1.10	[If Yes,]Result	○ Normal ○ Abnormal, not clinically significant ○ Abnormal, clinically significant

ECG		
1.1	Was the ECG performed?	○ Yes ○ No
1.2	[If No,]Specify reason	
1.3	Date of ECG	mm/dd/yyyy
1.4	[If Yes,]Results	○ Normal ○ Abnormal, not clinically significant ○ Abnormal, clinically significant