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

Height and weight	
Height	
Unit height	○ cm ○ in
Body Mass Index (BMI)	
Unit weight	○ kg ○ lb
BMI unit	○ kg/m2
Weight	

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

Adverse event	
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
Start date	mm/dd/yyyy
Location of AE	○ NA (Non-cutaneous) ○ Back ○ Scalp ○ Face ○ Chest ○ Arm ○ Leg ○ Trunk ○ Limb ○ Site 1 ○ Site 2 ○ Site 3 ○ Site 4
Was the AE related to IMP (Tdap vaccine)?	○ Probably related ○ Possibly related ○ Not related
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
Withdrawn from trial due to this AE?	○ Yes ○ No
Location of AE relative to treatment area	○ Non-cutaneous ○ Lesional/perilesional ○ Distant ○ Inside treatment area ○ Outside treatment area ○ Application area
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	
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
Did the adverse event start before the administration of the vaccines?	○ Yes ○ No
Is the event an adverse event of special interest?	○ Yes ○ No
Other action taken (tick all that apply)	☐ None ☐ Concomitant medication ☐ Concurrent procedure
Outcome	○ Fatal ○ Not recovered/not resolved ○ Recovering/resolving ○ Recovered/resolved ○ Recovered/resolved with sequelae ○ Unknown
AE identifier	
Adverse event	
Was the AE related to AxMP (TCS)?	○ Probably related ○ Possibly related ○ Not related
Ongoing	○ Yes ○ No
Was the AE related to IMP?	○ Probably related ○ Possibly related ○ Not related
Severity	○ Mild ○ Moderate ○ Severe

Adverse event	
Action taken with IMP	○ Dose not changed ○ Dose reduced ○ Dose increased ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Unknown
Stop date *Design note: Day can be unknown but month and year must be filled out*	mm/dd/yyyy
[if Yes,]Start time of AE	--:-- --
Did the AE start at the same day as CYP cocktail was given?	○ Yes ○ No
[If Yes,]Stop time of AE	--:-- --
Was the AE serious?	○ Yes ○ No
Action taken with AxMP (TCS)	○ Dose not changed ○ Dose reduced ○ Dose increased ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Unknown

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

Concomitant medication	
CM Number	
Medication or therapy (generic or brand name)	
[If Other,]Specify	
Route	○ Oral ○ Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○ Intramuscular ○ Respiratory (inhalation) ○ Intralesional ○ Intraperitoneal ○ Nasal ○ Vaginal ○ Rectal ○ Intravenous ○ Other
[If Topical,]Dose form	○ Cream ○ Lotion ○ Ointment ○ Other
Is this medication or therapy a rescue medication for chronic hand eczema?	○ Yes ○ No
[If Other,]Specify	
[If Other,]Specify	
Start date	mm/dd/yyyy
Stop date	mm/dd/yyyy
Ongoing	○ Yes ○ No
Unit	○ mcg ○ mg ○ g ○ Ml ○ Application ○ International Unit (IU) ○ Tablet ○ Capsule ○ Other
Dose per administration	
Indication	
Frequency	○ As needed (PRN) ○ Daily (QD) ○ Twice daily (BID) ○ Three times per day (TID) ○ Four times per day ○ Weekly (QS) ○ Monthly (QM) ○ Once ○ Other

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

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

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

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