

# CRF Specification for Test Trial abcd

Lorem ipsum dolor sit amet consectetur odio id et turpis vitae. Est risus congue pretium non Vestibulum ante dui risus Nam convallis. Semper vitae Sed lacus pretium ut tortor tempus felis massa pellentesque. Congue a odio ut Aenean libero hendrerit eros cursus arcu quis. Urna velit consequat ipsum Sed Aliquam.

**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		SDTM Annotation	Remarks	
Did the subject have any concurrent procedures/surgeries since screening?	<input type="radio"/> Yes <input type="radio"/> No	NOT SUBMITTED	<b>CRF text Annotation</b> <div> <div>Yes</div> <div>No</div> </div> <div> <div>Y</div> <div>N</div> </div>	
Did the subject take any concomitant medications?	<input type="radio"/> Yes <input type="radio"/> No	NOT SUBMITTED	<b>CRF text Annotation</b> <div> <div>Yes</div> <div>No</div> </div> <div> <div>Y</div> <div>N</div> </div>	
Did the subject have any adverse events since screening	<input type="radio"/> Yes <input type="radio"/> No	NOT SUBMITTED	<b>CRF text Annotation</b> <div> <div>Yes</div> <div>No</div> </div> <div> <div>Y</div> <div>N</div> </div>	
Did the subject have any other events involving IMP since screening? <i>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</i>	<input type="radio"/> Yes <input type="radio"/> No		<b>CRF text Annotation</b> <div> <div>Yes</div> <div>No</div> </div> <div> <div>Y</div> <div>N</div> </div> <i>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</i>	

Demographics		SDTM Annotation	Remarks	
[If Other, ]Specify	<input type="text"/>	QVAL, SUPPDM.QNAM=RACEOTH		
Age unit	<input type="radio"/> Year(s)	QVAL, SUPPDM.QNAM=AGEnU n is a consecutive counter starting from 1	<b>CRF text Annotation</b> Year(s)   YEARS	
Age	<input type="text"/>	QVAL, SUPPDM.QNAM=AGEn. Set SUPPDM.QNAM=AGEnVIS where QVAL=the visit where age is collected		
Date of birth	<input type="text"/> mm / dd / yyyy	BRTHDTC		
Ethnicity	<input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino	ETHNIC	<b>CRF text</b>	<b>Annotation</b>
			Hispanic or Latino Not Hispanic or Latino	HISPANIC OR LATINO NOT HISPANIC OR LATINO
Race	<input type="radio"/> White <input type="radio"/> Black or African American <input type="radio"/> Asian <input type="radio"/> American Indian or Alaska Native <input type="radio"/> Native Hawaiian or Other Pacific Islander <input type="radio"/> Other	RACE, if RACE=OTHER then value is set to NULL	<b>CRF text</b>	<b>Annotation</b>
			White Black or African American Asian American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other	WHITE BLACK OR AFRICAN AMERICAN ASIAN AMERICAN INDIAN OR ALASKA NATIVE NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER OTHER
Sex	<input type="radio"/> Male <input type="radio"/> Female	SEX	<b>CRF text Annotation</b>	
			Male Female	M F
Race	<input type="radio"/> White <input type="radio"/> Black or African American <input type="radio"/> Asian Japanese <input type="radio"/> Asian Other <input type="radio"/> American Indian or Alaska Native <input type="radio"/> Native Hawaiian or Other Pacific Islander <input type="radio"/> 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	<b>CRF text</b>	<b>Annotation</b>
			White Black or African American Asian Japanese Asian Other American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other	WHITE BLACK OR AFRICAN AMERICAN ASIAN ASIANd AMERICAN INDIAN OR ALASKA NATIVE NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER OTHER

Height and weight		SDTM Annotation	Remarks	
Height	<input type="text"/>	VSORRES, VSTESTCD=HEIGHT		
Unit height	<div><input type="radio"/> cm</div> <div><input type="radio"/> in</div>	VSORRESU, VSTESTCD=HEIGHT	<b>CRF text Annotation</b>	
			cm	cm
			in	in
Body Mass Index (BMI)	<input type="text"/>	VSORRES, VSTESTCD=BMI		
Unit weight	<div><input type="radio"/> kg</div> <div><input type="radio"/> lb</div>	VSORRESU, VSTESTCD=WEIGHT	<b>CRF text Annotation</b>	
			kg	kg
			lb	LB
BMI unit	<div><input type="radio"/> kg/m2</div>	VSORRESU, VSTESTCD=BMI	<b>CRF text Annotation</b>	
			kg/m2	kg/m2
Weight	<input type="text"/>	VSORRES, VSTESTCD=WEIGHT		

Urine pregnancy test		SDTM Annotation	Remarks	
[If Yes, ]Urine pregnancy test date	<input type="text" value="mm/dd/yyyy"/>	LBDTC, LBCAT=URINALYSIS, LBTESTCD=HCG, LBSPEC=URINE, LBSPID=COLLECTED		
[If Yes, ]Result	<input type="radio"/> Positive <input type="radio"/> Negative	LBORRES, LBCAT=URINALYSIS, LBTESTCD=HCG, LBSPEC=URINE, LBSPID=COLLECTED	<b>CRF text Annotation</b> Positive   POSITIVE Negative   NEGATIVE	
[If Yes, ]Was a urine pregnancy test performed?	<input type="radio"/> Yes <input type="radio"/> No	RPORRES, RPTESTCD=HCGDONE. If No then PRSTAT=NOT DONE	<b>CRF text Annotation</b> Yes   Y No   N	
Is the female of child-bearing potential?	<input type="radio"/> Yes <input type="radio"/> No	RPORRES, RPTESTCD=CHILDPOT	<b>CRF text Annotation</b> Yes   Y No   N	
[If No, ]Specify reason	<input type="text"/>	RPREASND		

Adverse event		SDTM Annotation	Remarks	
SAE criteria (Tick all that apply)	<input type="checkbox"/> Death	If ticked, set the relevant variable in AE to Y. If Fatal, set AESDTH. If Life-threatening set AESLIFE. If Hospitalisation set AESHOSP.	<b>CRF text</b>	<b>Annotation</b>
	<input type="checkbox"/> Life-threatening		Death	1
	<input type="checkbox"/> In-patient hospitalisation/prolongation of existing hospitalisation		Life-threatening	2
	<input type="checkbox"/> Persistent or significant disability/incapacity		In-patient hospitalisation/prolongation of existing hospitalisation	3
	<input type="checkbox"/> Congenital anomaly/birth defect		Persistent or significant disability/incapacity	4
	<input type="checkbox"/> Other medically important condition		Congenital anomaly/birth defect	5
			Other medically important condition	6
Start date	<input type="text" value="mm/dd/yyyy"/>	AESTDTC		
Location of AE	<input type="radio"/> NA (Non-cutaneous) <input type="radio"/> Back <input type="radio"/> Scalp <input type="radio"/> Face <input type="radio"/> Chest <input type="radio"/> Arm <input type="radio"/> Leg <input type="radio"/> Trunk <input type="radio"/> Limb <input type="radio"/> Site 1 <input type="radio"/> Site 2 <input type="radio"/> Site 3 <input type="radio"/> Site 4	AELOC, If value does not exist on LOC codelist then place in SUPPAE.QVAL where QNAM=ALTLOC.	<b>CRF text</b>	<b>Annotation</b>
			NA (Non-cutaneous)	NOT APPLICABLE
			Back	BACK
			Scalp	SCALP
			Face	FACE
			Chest	CHEST
			Arm	ARM
			Leg	LEG
			Trunk	TRUNK
			Limb	LIMB
			Site 1	SITE 1
			Site 2	SITE 2
			Site 3	SITE 3
			Site 4	SITE 4
Was the AE related to IMP (Tdap vaccine)?	<input type="radio"/> Probably related <input type="radio"/> Possibly related <input type="radio"/> Not related	QVAL, SUPPAE.QNAM=RELTDAP	<b>CRF text</b>	<b>Annotation</b>
			Probably related	PROBABLY RELATED
			Possibly related	POSSIBLY RELATED
			Not related	NOT RELATED
Was the AE related to IMP (meningococcal vaccine)? <i>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.</i>	<input type="radio"/> Probably related <input type="radio"/> Possibly related <input type="radio"/> Not related	QVAL, SUPPAE.QNAM=RELMENI	<b>CRF text</b>	<b>Annotation</b>
			Probably related	PROBABLY RELATED
			Possibly related	POSSIBLY RELATED
			Not related	NOT RELATED
			<i>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.</i>	
Withdrawn from trial due to this AE?	<input type="radio"/> Yes <input type="radio"/> No	QVAL, SUPPAE.QNAM=AEAWDR	<b>CRF text Annotation</b>	
			Yes	Y
No	N			
Location of AE relative to treatment area	<input type="radio"/> Non-cutaneous <input type="radio"/> Lesional/perilesional <input type="radio"/> Distant <input type="radio"/> Inside treatment area <input type="radio"/> Outside treatment area <input type="radio"/> Application area	QVAL, SUPPAE.QNAM=AERELTRT	<b>CRF text</b>	<b>Annotation</b>
			Non-cutaneous	NON-CUTANEOUS
			Lesional/perilesional	LESIONAL/PERILISIONAL
			Distant	DISTANT
			Inside treatment area	INSIDE TREATMENT AREA
			Outside treatment area	OUTSIDE TREATMENT AREA
			Application 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?	<input type="radio"/> Before dosing <input type="radio"/> After dosing <input type="radio"/> Not applicable	QVAL, SUPPAE.QNAM=AEOCCUR	<b>CRF text</b>	<b>Annotation</b>
			Before dosing	BEFORE DOSING
			After dosing	AFTER DOSING
			Not applicable	NA

Adverse event		SDTM Annotation	Remarks															
Did the adverse event start before the first administration of IMP? <i>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.</i>	<input type="radio"/> Yes <input type="radio"/> No	QVAL, SUPPAE.QNAM=AETRTEM	<b>CRF text Annotation</b> <table border="1"> <tr> <td>Yes</td> <td>Y</td> </tr> <tr> <td>No</td> <td>N</td> </tr> </table> <i>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.</i>		Yes	Y	No	N										
Yes	Y																	
No	N																	
Did the adverse event start before the administration of the vaccines?	<input type="radio"/> Yes <input type="radio"/> No	QVAL, SUPPAE.QNAM=AEOCCUR	<b>CRF text Annotation</b> <table border="1"> <tr> <td>Yes</td> <td>Y</td> </tr> <tr> <td>No</td> <td>N</td> </tr> </table>		Yes	Y	No	N										
Yes	Y																	
No	N																	
Is the event an adverse event of special interest?	<input type="radio"/> Yes <input type="radio"/> No	QVAL, SUPPAE.QNAM=AESI	<b>CRF text Annotation</b> <table border="1"> <tr> <td>Yes</td> <td>Y</td> </tr> <tr> <td>No</td> <td>N</td> </tr> </table>		Yes	Y	No	N										
Yes	Y																	
No	N																	
Other action taken (tick all that apply)	<input type="checkbox"/> None <input type="checkbox"/> Concomitant medication <input type="checkbox"/> Concurrent procedure	AEACNOTH, IF MULTIPLE ANSWERS ARE GIVEN SET AEACNOTH TO MULTIPLE AND STORE INDIVIDUAL ANSWERS IN SUPPAE	<table border="1"> <thead> <tr> <th>CRF text</th> <th>Annotation</th> </tr> </thead> <tbody> <tr> <td>None</td> <td>NONE</td> </tr> <tr> <td>Concomitant medication</td> <td>CONCOMITANT MEDICATION</td> </tr> <tr> <td>Concurrent procedure</td> <td>CONCURRENT PROCEDURE</td> </tr> </tbody> </table>		CRF text	Annotation	None	NONE	Concomitant medication	CONCOMITANT MEDICATION	Concurrent procedure	CONCURRENT PROCEDURE						
CRF text	Annotation																	
None	NONE																	
Concomitant medication	CONCOMITANT MEDICATION																	
Concurrent procedure	CONCURRENT PROCEDURE																	
Outcome	<input type="radio"/> Fatal <input type="radio"/> Not recovered/not resolved <input type="radio"/> Recovering/resolving <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Unknown	AEOUT	<table border="1"> <thead> <tr> <th>CRF text</th> <th>Annotation</th> </tr> </thead> <tbody> <tr> <td>Fatal</td> <td>FATAL</td> </tr> <tr> <td>Not recovered/not resolved</td> <td>NOT RECOVERED/NOT RESOLVED</td> </tr> <tr> <td>Recovering/resolving</td> <td>RECOVERING/RESOLVING</td> </tr> <tr> <td>Recovered/resolved</td> <td>RECOVERED/RESOLVED</td> </tr> <tr> <td>Recovered/resolved with sequelae</td> <td>RECOVERED/RESOLVED WITH SEQUELAE</td> </tr> <tr> <td>Unknown</td> <td>UNKNOWN</td> </tr> </tbody> </table>		CRF text	Annotation	Fatal	FATAL	Not recovered/not resolved	NOT RECOVERED/NOT RESOLVED	Recovering/resolving	RECOVERING/RESOLVING	Recovered/resolved	RECOVERED/RESOLVED	Recovered/resolved with sequelae	RECOVERED/RESOLVED WITH SEQUELAE	Unknown	UNKNOWN
CRF text	Annotation																	
Fatal	FATAL																	
Not recovered/not resolved	NOT RECOVERED/NOT RESOLVED																	
Recovering/resolving	RECOVERING/RESOLVING																	
Recovered/resolved	RECOVERED/RESOLVED																	
Recovered/resolved with sequelae	RECOVERED/RESOLVED WITH SEQUELAE																	
Unknown	UNKNOWN																	
AE identifier		AESPID																
Adverse event		AETERM																
Was the AE related to AxMP (TCS)?	<input type="radio"/> Probably related <input type="radio"/> Possibly related <input type="radio"/> Not related	AERELNST	<table border="1"> <thead> <tr> <th>CRF text</th> <th>Annotation</th> </tr> </thead> <tbody> <tr> <td>Probably related</td> <td>PROBABLY RELATED</td> </tr> <tr> <td>Possibly related</td> <td>POSSIBLY RELATED</td> </tr> <tr> <td>Not related</td> <td>NOT RELATED</td> </tr> </tbody> </table>		CRF text	Annotation	Probably related	PROBABLY RELATED	Possibly related	POSSIBLY RELATED	Not related	NOT RELATED						
CRF text	Annotation																	
Probably related	PROBABLY RELATED																	
Possibly related	POSSIBLY RELATED																	
Not related	NOT RELATED																	
Ongoing	<input type="radio"/> Yes <input type="radio"/> No	AEENRTPT, If ONGOING then AEENTPT=END OF TRIAL	<b>CRF text Annotation</b> <table border="1"> <tr> <td>Yes</td> <td>Y</td> </tr> <tr> <td>No</td> <td>N</td> </tr> </table>		Yes	Y	No	N										
Yes	Y																	
No	N																	



Adverse event		SDTM Annotation	Remarks	
Was the AE related to IMP?	<input type="radio"/> Probably related <input type="radio"/> Possibly related <input type="radio"/> Not related	AEREL	<b>CRF text</b>	<b>Annotation</b>
			Probably related	PROBABLY RELATED
			Possibly related	POSSIBLY RELATED
			Not related	NOT RELATED
Severity	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	AESEV	<b>CRF text</b>	<b>Annotation</b>
			Mild	MILD
			Moderate	MODERATE
			Severe	SEVERE
Action taken with IMP	<input type="radio"/> Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Dose increased <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown	AEACN	<b>CRF text</b>	<b>Annotation</b>
			Dose not changed	DOSE NOT CHANGED
			Dose reduced	DOSE REDUCED
			Dose increased	DOSE INCREASED
			Drug interrupted	DRUG INTERRUPTED
			Drug withdrawn	DRUG WITHDRAWN
			Not applicable	NOT APPLICABLE
			Unknown	UNKNOWN
Stop date <i>Design note: Day can be unknown but month and year must be filled out</i>	<input type="text" value="mm/dd/yyyy"/>	AEENDTC	<i>Design note: Day can be unknown but month and year must be filled out</i>	
[if Yes, ]Start time of AE	<input type="text" value="--:-- --"/>	QVAL, SUPPAE.QNAM=AESTDTC		
Did the AE start at the same day as CYP cocktail was given?	<input type="radio"/> Yes <input type="radio"/> No	QVAL, SUPPAE.QNAM=CYPTRTEM	<b>CRF text</b>	<b>Annotation</b>
			Yes	Y
			No	N
[If Yes, ]Stop time of AE	<input type="text" value="--:-- --"/>	QVAL, SUPPAE.QNAM=AEENDTC		
Was the AE serious?	<input type="radio"/> Yes <input type="radio"/> No	AESER	<b>CRF text</b>	<b>Annotation</b>
			Yes	Y
			No	N
Action taken with AxMP (TCS)	<input type="radio"/> Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Dose increased <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown	QVAL, SUPPAE.QNAM=AEACNNST	<b>CRF text</b>	<b>Annotation</b>
			Dose not changed	DOSE NOT CHANGED
			Dose reduced	DOSE REDUCED
			Dose increased	DOSE INCREASED
			Drug interrupted	DRUG INTERRUPTED
			Drug withdrawn	DRUG WITHDRAWN
			Not applicable	NOT APPLICABLE
			Unknown	UNKNOWN

Urine dipstick		SDTM Annotation	Remarks	
[If No, ]Specify reason	<div></div>	LBREASND, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED, LBMETHOD=DIPSTICK.		
Was a urine sample tested with a dipstick?	<div><div></div> Yes</div> <div><div></div> No</div>	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.	<div><div>CRF text Annotation</div><div><div>Yes</div><div>Y</div></div><div><div>No</div><div>N</div></div></div>	
[If Yes, ]Result	<div><div></div> Normal</div> <div><div></div> Abnormal</div>	LBORRES, LBCAT=URINALYSIS, LBTESTCD=INTP, LBSPEC=URINE, LBSPID=COLLECTED, LBMETHOD=DIPSTICK.	<div><div>CRF text Annotation</div><div><div>Normal</div><div>NORMAL</div></div><div><div>Abnormal</div><div>ABNORMAL</div></div></div>	

Concomitant medication		SDTM Annotation	Remarks	
CM Number	<input type="text"/>	CMSPID		
Medication or therapy (generic or brand name)	<input type="text"/>	CMTRT		
[If Other, ]Specify	<input type="text"/>	QVAL, SUPPCM.QNAM = DOSUOTH		
Route	<input type="radio"/> Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> Respiratory (inhalation) <input type="radio"/> Intralesional <input type="radio"/> Intraperitoneal <input type="radio"/> Nasal <input type="radio"/> Vaginal <input type="radio"/> Rectal <input type="radio"/> Intravenous <input type="radio"/> Other	CMROUTE	<b>CRF text</b> Oral Topical Subcutaneous Transdermal Intraocular Intramuscular Respiratory (inhalation) Intralesional Intraperitoneal Nasal Vaginal Rectal Intravenous Other	<b>Annotation</b> ORAL TOPICAL SUBCUTANEOUS TRANSDERMAL INTRAOCULAR INTRAMUSCULAR RESPIRATORY (INHALATION) INTRALESIONAL INTRAPERITONEAL NASAL VAGINAL RECTAL INTRAVENOUS OTHER
[If Topical, ]Dose form	<input type="radio"/> Cream <input type="radio"/> Lotion <input type="radio"/> Ointment <input type="radio"/> Other	CMDOSFRM	<b>CRF text</b> Cream Lotion Ointment Other	<b>Annotation</b> CREAM LOTION OINTMENT OTHER
Is this medication or therapy a rescue medication for chronic hand eczema?	<input type="radio"/> Yes <input type="radio"/> No	QVAL, SUPPCM.QNAM=RESCMED	<b>CRF text</b> Yes No	<b>Annotation</b> Y N
[If Other, ]Specify	<input type="text"/>	QVAL, SUPPCM.QNAM = FRQOTH		
[If Other, ]Specify	<input type="text"/>	QVAL, SUPPCM.QNAM=FRMOTH		
Start date	<input type="text" value="mm / dd / yyyy"/>	CMSTDTC		
Stop date	<input type="text" value="mm / dd / yyyy"/>	CMENDTC		
Ongoing	<input type="radio"/> Yes <input type="radio"/> No	CMENRTPT, CMMENTPT=END OF TRIAL	<b>CRF text</b> Yes No	<b>Annotation</b> Y N
Unit	<input type="radio"/> mcg <input type="radio"/> mg <input type="radio"/> g <input type="radio"/> Ml <input type="radio"/> Application <input type="radio"/> International Unit (IU) <input type="radio"/> Tablet <input type="radio"/> Capsule <input type="radio"/> Other	CMDOSU	<b>CRF text</b> mcg mg g Ml Application International Unit (IU) Tablet Capsule Other	<b>Annotation</b> ug mg g mL APPLICATION IU TABLET CAPSULE OTHER
Dose per administration	<input type="text"/>	CMDOSTXT, If CMDOSTXT is a numeric value, then transfer the number to the numeric field CMDOSE, and set CMDOSTXT to null		
Indication	<input type="text"/>	CMINDC		

Concomitant medication		SDTM Annotation	Remarks	
Frequency	<div><input type="radio"/> As needed (PRN)</div> <div><input type="radio"/> Daily (QD)</div> <div><input type="radio"/> Twice daily (BID)</div> <div><input type="radio"/> Three times per day (TID)</div> <div><input type="radio"/> Four times per day</div> <div><input type="radio"/> Weekly (QS)</div> <div><input type="radio"/> Monthly (QM)</div> <div><input type="radio"/> Once</div> <div><input type="radio"/> Other</div>	CMDOSFRQ	CRF text	Annotation
			As needed (PRN)	PRN
			Daily (QD)	QD
			Twice daily (BID)	BID
			Three times per day (TID)	TID
			Four times per day	QID
			Weekly (QS)	EVERY WEEK
			Monthly (QM)	QM
			Once	ONCE
			Other	OTHER

Blood biomarkers		SDTM Annotation	Remarks	
[If No, ]Specify reason		LBREASND, LBCAT=BIOMARKER, LBTESTCD=SAMPLE, LBSPEC=SERUM, LBSPID=COLLECTED.		
Was sampling performed for blood biomarkers?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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.	<div>CRF text</div> Yes No Not applicable	<div>Annotation</div> Y N NA
Did the subject sign the additional informed consent for biomarkers?	<input type="radio"/> Yes <input type="radio"/> No	DSDECOD, DSCAT=PROTOCOL MILESTONE. If No then create no record. If Yes then DSTERM=INFORMED CONSENT FOR ADDITIONAL BIOMARKERS, DSDECOD=INFORMED CONSENT OBTAINED	<div>CRF text</div> Yes No	<div>Annotation</div> Y N
[If Yes, ]Provide date the consent was signed	mm / dd / yyyy	DSSTDTC		

Concurrent procedures		SDTM Annotation	Remarks	
Inside treatment area?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Not applicable	QVAL, SUPPPR.QNAM=INTRTAR	CRF text	Annotation
			Yes	Y
			No	N
			Unknown	U
			Not applicable	NA
Indication	<input type="text"/>	PRINDC		
Start date	<input type="text" value="mm/dd/yyyy"/>	PRSTDTC		
Procedure name	<input type="text"/>	PRTRT		
Ongoing	<input type="radio"/> Yes <input type="radio"/> No	PRENRTPT, PRENTPT=END OF TRIAL	CRF text Annotation	
			Yes	Y
			No	N
Body location	<input type="radio"/> Head <input type="radio"/> Trunk <input type="radio"/> Upper limb <input type="radio"/> Lower limb	PRLOC	CRF text	Annotation
			Head	HEAD
			Trunk	TRUNK
			Upper limb	LIMB, UPPER
			Lower limb	LIMB, LOWER
Procedure number	<input type="text"/>	PRSPID		
Procedure name (include anatomical area if relevant)	<input type="text"/>	PRTRT		
	<input type="text"/>			
Stop date	<input type="text" value="mm/dd/yyyy"/>	PRENDTC		

Central laboratory		SDTM Annotation	Remarks	
[If Yes, ]Result	<input type="radio"/> Normal <input type="radio"/> Abnormal, not clinically significant <input type="radio"/> Abnormal, clinically significant	LBORRES, If Clinically Significant SUPPLB.QVAL=Y(QNAM=LBCLSIG),if Not Clinically significant SUPPLB.QVAL=N(QNAM=LBCLSIG)	CRF text	Annotation
			Normal	NORMAL
			Abnormal, not clinically significant	ABNORMAL - NOT CLINICALLY SIGNIFICANT
			Abnormal, clinically significant	ABNORMAL - CLINICALLY SIGNIFICANT
Was a urine sample sent for urinalysis?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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.	CRF text	Annotation
Yes	Y			
No	N			
Not applicable	NA			
[If Yes, ]Result	<input type="radio"/> Normal <input type="radio"/> Abnormal, not clinically significant <input type="radio"/> Abnormal, clinically significant	LBORRES, LBCAT=BLOOD ANALYSIS, LBTESTCD=INTP, LBSPEC=BLOOD, LBSPID=COLLECTED. If Normal LBORRES=NORMAL, if Abnormal LBORRES=ABNORMAL.	CRF text	Annotation
Normal	NORMAL			
Abnormal, not clinically significant	ABNORMAL - NOT CLINICALLY SIGNIFICANT			
Abnormal, clinically significant	ABNORMAL - CLINICALLY SIGNIFICANT			
[If No, ]Specify reason	<input type="text"/>	LBREASND, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED.		
[If No, ]Specify reason	<input type="text"/>	LBREASND, LBCAT=BLOOD ANALYSIS, LBTESTCD=SAMPLE, LBSPEC=BLOOD, LBSPID=COLLECTED.		
[If Yes, ]Time of sampling	<input type="text" value="-- : -- --"/>	LBDTC, LBCAT=BLOOD ANALYSIS, LBTESTCD=SAMPLE, LBSPEC=BLOOD, LBSPID=COLLECTED.		
Was blood sampling performed?	<input type="radio"/> Yes <input type="radio"/> 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.	CRF text	Annotation
Yes	Y			
No	N			
[If Yes, ]Date of sampling	<input type="text" value="mm / dd / yyyy"/>	LBDTC, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED.		
[If Yes, ]Date of sampling	<input type="text" value="mm / dd / yyyy"/>	LBDTC, LBCAT=BLOOD ANALYSIS, LBTESTCD=SAMPLE, LBSPEC=BLOOD, LBSPID=COLLECTED.		
[If Yes, ]Time of sampling	<input type="text" value="-- : -- --"/>	LBDTC, LBCAT=URINALYSIS, LBTESTCD=SAMPLE, LBSPEC=URINE, LBSPID=COLLECTED.		

ECG		SDTM Annotation	Remarks					
Was the ECG performed?	<input type="radio"/> Yes <input type="radio"/> No	EGORRES, EGTESTCD=INTP. If Yes then use EGORRES for the result. If No then EGSTAT=NOT DONE and populate EGREASND.	<b>CRF text Annotation</b> <table> <tr> <td>Yes</td> <td>Y</td> </tr> <tr> <td>No</td> <td>N</td> </tr> </table>		Yes	Y	No	N
Yes	Y							
No	N							
[If No, ]Specify reason	<input type="text"/>	EGREASND, EGTESTCD=INTP						
[If Yes, ]Results	<input type="radio"/> Normal <input type="radio"/> Abnormal, not clinically significant <input type="radio"/> 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)	<b>CRF text</b> Normal Abnormal, not clinically significant Abnormal, clinically significant	<b>Annotation</b> NORMAL ABNORMAL - NOT CLINICALLY SIGNIFICANT ABNORMAL - CLINICALLY SIGNIFICANT				
Date of ECG	<input type="text" value="mm/dd/yyyy"/>	EGDTC, EGTESTCD=INTP						



