Subject Case Report Forms

V5.000 PROD SLF 15MAY2025 - Unique

Signature Prompt: I have reviewed all the information for the subject and I believe it to be true and accurate to the best of my knowledge.

Site Number (Derived via Add Participant) _____ ①

Participant Number (Derived via Add Participant) _____ ②

Participant ID (Derived via Add Participant) _____ ③

Note Participant ID is the combination of Site Number and Participant Number.

Click 'Save' to allocate the next available Participant Number and create the subject.

eCRF_Completion_Guidelines _____ ⑤

Last Saved _____ ⑥

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① SITEID	$7				SITEID
② SUBJNUM	$3				SUBJNUM
③ SUBJID	$11				SUBJID
⑤ CCG	$1				CCG
⑥ H_NOW	dd MMM yyyy HH:nn:ss				H_NOW

Was the visit performed? Yes ◯ **①**
No ◯

If No, please provide reason _____ **②**

Visit date (DD/MMM/YYYY) _____ **③**

Current Protocol Version (Derived) Version 1.0 ◯ **④**
Version 2.0 ◯
Version 3.0 ◯
Version 4.0 ◯
Version 5.0 ◯
Version 6.0 ◯
Version 7.0 ◯
Version 8.0 ◯
Version 9.0 ◯
Version 10.0 ◯

Z_FOLDER (EDC Purposes) _____ **⑤**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	SVYN	$1		Y = Yes N = No		SVYN
2	SVREAS	$200				SVREAS
3	SVDAT	dd MMM yyyy				SVDAT
4	Z_PV	2		1 = Version 1.0 2 = Version 2.0 3 = Version 3.0 4 = Version 4.0 5 = Version 5.0 6 = Version 6.0 7 = Version 7.0 8 = Version 8.0 9 = Version 9.0 10 = Version 10.0		Z_PV
5	Z_FOLDER	$25				Z_FOLDER

Date of Visit (DD/MMM/YYYY) _____ ①

Reason for unscheduled visit _____ ②

Select the assessment/s which were performed at this unscheduled visit

UNSCHEDULED CHEST X-RAY _____ ④

URINE PREGNANCY TEST _____ ⑤

CENTRAL LABORATORY - SERUM PREGNANCY TEST _____ ⑥

CENTRAL LABORATORY - HEMATOLOGY, SERUM CHEMISTRY AND URINALYSIS _____ ⑦

CENTRAL LABORATORY - SEROLOGY _____ ⑧

CENTRAL LABORATORY - COAGULATION PANEL _____ ⑨

CENTRAL LABORATORY - FASTING LIPID PANEL _____ ⑩

CENTRAL LABORATORY - TUBERCULOSIS (IGRA) _____ ⑪

CENTRAL LABORATORY - THYROID (FT3, FT4 AND TSH) _____ ⑫

CENTRAL LABORATORY - SERUM ADA _____ ⑬

CENTRAL LABORATORY - ESTRADIOL TEST _____ ⑭

CENTRAL LABORATORY - FOLLICLE STIMULATING HORMONE TEST ⑮

LOCAL LABORATORY HEMATOLOGY ⑯

LOCAL LABORATORY SEROLOGY ⑰

LOCAL LABORATORY CLINICAL CHEMISTRY ⑱

LOCAL LABORATORY URINALYSIS - MACROSCOPIC PANEL (DIPSTICK) ⑲

LOCAL LABORATORY URINALYSIS - MICROSCOPIC PANEL ⑳

LOCAL LABORATORY LIPID PANEL ㉑

LOCAL LABORATORY THYROID ㉒

LOCAL LABORATORY COAGULATION PANEL ㉓

LOCAL LABORATORY TEST TUBERCULOSIS (IGRA) ㉔

LOCAL LABORATORY HbA1c ㉕

LOCAL LABORATORY HORMONE TEST ㉖

CENTRAL LABORATORY - PHARMACOKINETICS (PK) SAMPLING ㉗

CENTRAL LABORATORY - SERUM hs-CRP AND IL-6 _____ (28)

CENTRAL LABORATORY - TRAb _____ (29)

CENTRAL LABORATORY - TSI _____ (30)

CENTRAL LABORATORY - HbA1c _____ (31)

PHYSICAL EXAMINATION _____ (32)

VITAL SIGNS (VISIT WITHOUT STUDY TREATMENT) _____ (33)

12-LEAD ECG CENTRAL READER _____ (34)

WEIGHT, HEIGHT AND BMI _____ (35)

GRAVES OPHTHALMOPATHY QUALITY OF LIFE SCALE (GO-QOL) _____ (36)

UNSCHEDULED OCULAR EXAM _____ (37)

UNSCHEDULED OCULAR EXAM CONTINUED - SLIT LAMP EXAMINATION _____ (38)

UNSCHEDULED OCULAR EXAM CONTINUED - OPHTHALMOSCOPY _____ (39)

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	UNSDATE	dd MMM yyyy				UNSDATE
2	UNSREAS	$200				UNSREAS
4	UNSXRUNS	1				UNSXRUNS
5	UNSPREG	1				UNSPREG
6	UNSPREG2	1				UNSPREG2
7	UNSCLHM	1				UNSCLHM
8	UNSSER	1				UNSSER
9	UNSCOAG	1				UNSCOAG
10	UNSLIP	1				UNSLIP
11	UNSTUB	1				UNSTUB
12	UNSTHY	1				UNSTHY
13	UNSSE	1				UNSSE
14	UNSEST	1				UNSEST

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15	UNSFOLL	1				UNSFOLL
16	UNSHEM	1				UNSHEM
17	UNSSERU	1				UNSSERU
18	UNSCHEM	1				UNSCHEM
19	UNSURI	1				UNSURI
20	UNSURI2	1				UNSURI2
21	UNSLIPU	1				UNSLIPU
22	UNSTHYU	1				UNSTHYU
23	UNSCOAGU	1				UNSCOAGU
24	UNSTUBU	1				UNSTUBU
25	UNSHBA1C	1				UNSHBA1C
26	UNSHORM	1				UNSHORM
27	UNSCLPK	1				UNSCLPK

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
28	UNSCLSER	1				UNSCLSER
29	UNSTRAB	1				UNSTRAB
30	UNSTSI	1				UNSTSI
31	UNSCHBA1 C	1				UNSCHBA1 C
32	UNSPE	1				UNSPE
33	UNSVS	1				UNSVS
34	UNSECG	1				UNSECG
35	UNSWEI	1				UNSWEI
36	UNSGRVS	1				UNSGRVS
37	UNSOCUL	1				UNSOCUL
38	UNSSLIT	1				UNSSLIT
39	UNSOPTH	1				UNSOPTH

Was the Pre-Screening Informed Consent obtained?　Yes ◯ **①**
No ◯

Date of Pre-Screening Informed Consent
(DD/MMM/YYYY)

②

_____

Protocol Version

Version 1.0 ◯ **③**
Version 2.0 ◯
Version 3.0 ◯
Version 4.0 ◯
Version 5.0 ◯
Version 6.0 ◯
Version 7.0 ◯
Version 8.0 ◯
Version 9.0 ◯
Version 10.0 ◯

ICF Version (X.X)-OBSOLETE

_____ **④**

ICF IRB Approval Date (DD/MMM/YYYY)

_____ **⑤**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① ICPSYN	$1		Y = Yes N = No		ICPSYN
② ICPSDAT	dd/MMM/yy yy				ICPSDAT
③ ICPROTV	2		1 = Version 1.0 2 = Version 2.0 3 = Version 3.0 4 = Version 4.0 5 = Version 5.0 6 = Version 6.0 7 = Version 7.0 8 = Version 8.0 9 = Version 9.0 10 = Version 10.0		ICPROTV
④ ICFVERS	3.1				ICFVERS
⑤ ICPSIRBDA T	dd/MMM/yy yy				ICPSIRBDA T

Was the informed consent obtained?   Yes ◯ **1**
                                                       No ◯

Date of informed consent (DD/MMM/YYYY)   _____ **2**

Protocol Version   Version 1.0 ◯ **3**
                                           Version 2.0 ◯
                                           Version 3.0 ◯
                                           Version 4.0 ◯
                                           Version 5.0 ◯
                                           Version 6.0 ◯
                                           Version 7.0 ◯
                                           Version 8.0 ◯
                                           Version 9.0 ◯
                                          Version 10.0 ◯

Tourmaline ICF Version (X.X)-OBSOLETE   _____ **4**

ICF IRB Approval Date (DD/MMM/YYYY)   _____ **5**

Did the participant re-consent?   Yes ◯ **6**
                                                       No ◯

Date informed re-consent   **7**
(DD/MMM/YYYY)   _____

Protocol version reconsented to   Version 1.0 ◯ **8**
                                           Version 2.0 ◯
                                           Version 3.0 ◯

Version 4.0 ◯
Version 5.0 ◯
Version 6.0 ◯
Version 7.0 ◯
Version 8.0 ◯
Version 9.0 ◯
Version 10.0 ◯

Tourmaline ICF Version
reconsented to (X.X)-OBSOLETE ⑨
_____

ICF IRB Approval Date (DD/MMM/YYYY) _____ ⑩

Was pregnant partner consent provided? Yes ◯ ⑪
No ◯
NA ◯

Date pregnant partner consent signed (DD/MMM/YYYY) _____ ⑫

Was the participant re-screened? Yes ◯ ⑬
No ◯

If Yes, please record previous Participant ID ⑭
'(XXX-XXX-XXX)' _____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	ICYN	$1		Y = Yes N = No		ICYN
2	ICDAT	dd/MMM/yy yy				ICDAT
3	ICPROTV	2		1 = Version 1.0 2 = Version 2.0 3 = Version 3.0 4 = Version 4.0 5 = Version 5.0 6 = Version 6.0 7 = Version 7.0 8 = Version 8.0 9 = Version 9.0 10 = Version 10.0		ICPROTV
4	ICTOUV	3.1				ICTOUV
5	ICIRBDAT	dd/MMM/yy yy				ICIRBDAT

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑥ ICPARTREC	$1		Y = Yes N = No		ICPARTREC
⑦ ICRECDAT	dd/MMM/yy yy				ICRECDAT
⑧ ICRECVER	2		1 = Version 1.0 2 = Version 2.0 3 = Version 3.0 4 = Version 4.0 5 = Version 5.0 6 = Version 6.0 7 = Version 7.0 8 = Version 8.0 9 = Version 9.0 10 = Version 10.0		ICRECVER
⑨ ICRECTOUV	3.1				ICRECTOUV
⑩ ICRIRBDAT	dd/MMM/yy yy				ICRIRBDAT

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(11) ICPREGCON	$2		Y = Yes N = No NA = NA		ICPREGCON
(12) ICPREGDAT	dd/MMM/yy yy				ICPREGDAT
(13) ICPARTRES	$1		Y = Yes N = No		ICPARTRES
(14) ICPARTID	$11				ICPARTID

Did the participant meet all eligibility criteria?

Yes ◯ **1**
No ◯

Please select the Study Eye

Right Eye (OD) ◯ **2**
Left Eye (OS) ◯

Please select the Fellow Eye

Right Eye (OD) ◯ **3**
Left Eye (OS) ◯

If no, enter all criteria which were NOT met below

Criteria Type

Inclusion ◯ **5**
Exclusion ◯

Criteria Number

_____ **6**

Is the participant a screen failure?

Yes ◯ **7**
No ◯

If Yes, specify the main reason

Adverse Event ◯ **8**
Failure to meet eligibility ◯
criteria
Withdrawal by Participant ◯
Other ◯

If Adverse Event, please select AE
(Dynamic Search List)

_____ **9**

If Other, please specify

_____ **10**

Please enter date of screen failure (DD/MMM/YYYY) _____ ⑪

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	IEYN	$1		Y = Yes N = No		IEYN
2	IESE	$1		1 = Right Eye (OD) 2 = Left Eye (OS)		IESE
3	IEFE	$1		1 = Right Eye (OD) 2 = Left Eye (OS)		IEFE
5	IECAT	$1		1 = Inclusion 2 = Exclusion		IECAT
6	IECRIT	$3		IncExc		IECRIT
7	IESCF	$1		Y = Yes N = No		IESCF
8	IEREAS	$2		1 = Adverse Event 2 = Failure to meet eligibility criteria		IEREAS

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Withdrawal by Participant 4 = Other		
⑨ IEAES	$200				IEAES
⑩ IEOTH	$200				IEOTH
⑪ IESFDAT	dd/MMM/yyyy				IESFDAT

Did the participant meet all eligibility criteria?　　Yes ◯ **1**
　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

If no, enter all criteria which were NOT met below

Criteria Type　　　　　　　　　　　　　　Inclusion ◯ **3**
　　　　　　　　　　　　　　　　　　　Exclusion ◯

Criteria Number　　　　　　　_____ **4**

Is the participant a screen failure?　　　　Yes ◯ **5**
　　　　　　　　　　　　　　　　　　　　　No ◯

If Yes, specify the main reason　　　　　　　Adverse Event ◯ **6**
　　　　　　　　　　　Failure to meet eligibility ◯
　　　　　　　　　　　　　　　　　　criteria
　　　　　　　　　　Withdrawal by Participant ◯
　　　　　　　　　　　　　　　　　　　Other ◯

If Adverse Event, please select AE　　　　　　　　　 **7**
(Dynamic Search List)　　　　　　_____

If Other, please specify　　　　　_____ **8**

Please enter date of screen failure (DD/MMM/YYYY)　_____ **9**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	IEYN	$1		Y = Yes N = No		IEYN
3	IECAT	$1		1 = Inclusion 2 = Exclusion		IECAT
4	IECRIT	$3		IncExc		IECRIT
5	IESCF	$1		Y = Yes N = No		IESCF
6	IEREAS	$2		1 = Adverse Event 2 = Failure to meet eligibility criteria 3 = Withdrawal by Participant 4 = Other		IEREAS
7	IEAE1	$200				IEAE1
8	IEOTH	$200				IEOTH

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⊚ IESFDAT	dd/MMM/yy yy				IESFDAT

Month and Year of birth (MMM/YYYY) _____ ①

Age at Consent [Derived] _____ ②

Sex Assigned at Birth   Male ◯ ③
                                                 Female ◯

If female, is the participant of childbearing potential per   Yes ◯ ④
the protocol?   No ◯

If No, please provide reason   Surgical sterilization or ◯ ⑤
                                                  Hysterectomy
                                      Bilateral salpingectomy ◯
                                       Bilateral oophorectomy ◯
                                       Post-menopausal more ◯
                                             than 12 months
                                                       Other ◯

If Other, please specify _____ ⑥

Method of contraception   Implantable ◯ ⑦
                                    progestogen-only hormone
                                     contraception associated
                                  with inhibition of ovulation
                                        Intrauterine device ◯
                                               Intrauterine ◯
                                   hormone-releasing system
                                        Azoospermic partner ◯
                                     Combined (estrogen- and ◯
                                     progestogen-containing)
                                     hormonal contraception
                                      associated with inhibition
                                                of ovulation

	Progestogen-only hormone contraception associated with inhibition of ovulation ◯
	Sexual Abstinence ◯
	Bilateral tubal occlusion ◯
	Other ◯

If Other, please specify	_____ (8)

Provide the route of contraception for Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation	Oral ◯ (9)
	Intravaginal ◯
	Transdermal ◯

Provide the route of contraception for Progestogen-only hormone contraception associated with inhibition of ovulation	Oral ◯ (10)
	Injectable ◯

Race

White	_____ (12)

Black or African American	_____ (13)

Asian	_____ (14)

American Indian or Alaska Native	_____ (15)

Native Hawaiian or Other Pacific Islander	_____ (16)

Unknown	_____ (17)

Other _____ (18)

If Other, please specify _____ (19)

Ethnicity

Hispanic or Latino ◯ (20)
Not Hispanic or Latino ◯
Not Reported ◯
Unknown ◯

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	MYOB	MMM/yyyy				MYOB
2	AGE	3				AGE
3	GENDER	$1		M = Male F = Female		GENDER
4	CBYN	$1		Y = Yes N = No		CBYN
5	CBREAS	$2		1 = Surgical sterilization or Hysterectomy 2 = Bilateral salpingectomy 3 = Bilateral oophorectomy 4 = Post-menopausal more than 12 months 99 = Other		CBREAS
6	CBREASOTHR	$200				CBREASOTHR

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ METHCON	$2		1 = Implantable progestogen-only hormone contraception associated with inhibition of ovulation 2 = Intrauterine device 3 = Intrauterine hormone-releasing system 4 = Azoospermic partner 5 = Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation		METHCON

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Progestogen-only hormone contraception associated with inhibition of ovulation 7 = Sexual Abstinence 8 = Bilateral tubal occlusion 99 = Other		
(8) METHOTHR	$200				METHOTHR
(9) ROUTCON	$1		1 = Oral 2 = Intravaginal 3 = Transdermal		ROUTCON
(10) ROUTCON1	$1		1 = Oral 2 = Injectable		ROUTCON1
(17) RACE1	1				RACE1

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(13)	RACE2	1				RACE2
(14)	RACE3	1				RACE3
(15)	RACE4	1				RACE4
(16)	RACE5	1				RACE5
(17)	RACE6	1				RACE6
(18)	RACE7	1				RACE7
(19)	RACEOTH	$200				RACEOTH
(20)	ETHNIC	$1		1 = Hispanic or Latino 2 = Not Hispanic or Latino 3 = Not Reported 4 = Unknown		ETHNIC

Graves' disease: Start Date (DD/MMM/YYYY) [Allow partial date i.e. UN/UNK/YYYY] ①

_____

Active Thyroid Eye Disease (TED): Start Date (DD/MMM/YYYY) [Allow partial date i.e. UN/MMM/YYYY] ②

_____

Does the participant have any relevant medical condition or has the participant undergone any surgery prior to informed consent?   Yes ◯ ③   No ◯

If Yes, please enter details below: If an ocular event involves both eyes, please enter separate entries for each eye

Medical Condition or Event   _____ ⑤

Is this an ocular condition?   Yes ◯ ⑥   No ◯

If Yes, please enter any additional pertinent information _____ ⑦

If Ocular, select affected eye   Right Eye (OD) ◯ ⑧   Left Eye (OS) ◯

Start Date (DD/MMM/YYYY) [Allow partial date i.e. UN/UNK/YYYY] ⑨

_____

Start date unknown   _____ ⑩

Ongoing   _____ ⑪

End Date (DD/MMM/YYYY) [Allow partial date i.e. UN/UNK/YYYY] _____ **17**

End Date unknown _____ **13**

Severity   Grade 1 ◯ **14**
                                        Grade 2 ◯
                                        Grade 3 ◯

Requiring active treatment   Yes ◯ **15**
                                                No ◯

derived Hidden field for CFs _____ **16**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	MOSGHDT	dd-/MMM-/yyyy				MOSGHDT
②	MOSHTDT	dd-/MMM/yyy				MOSHTDT
③	MOSHSURG	$1		Y = Yes N = No		MOSHSURG
⑤	MOSHTERM	$200				MOSHTERM
⑥	MOSHOCUL	$1		Y = Yes N = No		MOSHOCUL
⑦	MOSHSPEC	$200				MOSHSPEC
⑧	MOSHOCEY	$1		1 = Right Eye (OD) 2 = Left Eye (OS)		MOSHOCEY
⑨	MOSHSTDT	dd-/MMM-/yyyy				MOSHSTDT
⑩	MOSHSTUN	1				MOSHSTUN
⑪	MOSHONG	1				MOSHONG

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
12	MOSHENDT	dd-/MMM-/ yyyy				MOSHENDT
13	MOSHENUN	1				MOSHENUN
14	MOSHSEV	$1		1 = Grade 1 2 = Grade 2 3 = Grade 3		MOSHSEV
15	MOSHTRT	$1		Y = Yes N = No		MOSHTRT
16	H_NOW	dd MMM yyyy HH:nn:ss				H_NOW

Has the participant ever used tobacco?   Yes ◯ **1**
                                           No ◯

Usage   Previous ◯ **2**
                                        Current ◯

Type of tobacco   Cigarettes ◯ **3**
                                    e-Cigarettes ◯
                                          Cigars ◯
                              Smokeless tobacco ◯
                                            Pipe ◯

What is/was the amount?   _____ **4**

What is/was the unit?   Pack ◯ **5**
                                      Cigarette ◯
                                           Cigar ◯
                                      Milliliter ◯
                                            Pipe ◯
                                      Cartridge ◯
                                           Pouch ◯

Frequency   Daily ◯ **6**
                                    Once Weekly ◯
                                        Monthly ◯
                                        Per Year ◯

Start date (DD/MMM/YYYY)   _____ **7**

Ongoing?   ⑧

End date (DD/MMM/YYYY)   ⑨

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① STUYN	$1		Y = Yes N = No		STUYN
② STUUSE	$1		1 = Previous 2 = Current		STUUSE
③ STUTYPE	$1		1 = Cigarettes 2 = e-Cigarettes 3 = Cigars 4 = Smokeless tobacco 5 = Pipe		STUTYPE
④ STUAMNT	4.2				STUAMNT
⑤ STUNIT	$1		1 = Pack 2 = Cigarette 3 = Cigar 4 = Milliliter 5 = Pipe 6 = Cartridge 7 = Pouch		STUNIT
⑥ STUFREQ	$1		1 = Daily 2 = Once Weekly		STUFREQ

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Monthly 4 = Per Year		
⑦ STUSTDT	dd-/MMM-/yyyy				STUSTDT
⑧ STUONG	1				STUONG
⑨ STUENDT	dd-/MMM-/yyyy				STUENDT

Chest X-ray performed at   Screening ◯ **1**
                                                          Prior to screening ◯

Date of X-ray (DD/MMM/YYYY)   _____ **2**

Result   Normal ◯ **3**
                                                     Abnormal, clinically ◯
                                                                 significant
                                                 Abnormal, not clinically ◯
                                                                 significant

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If Abnormal - Was there any evidence for active   Yes ◯ **4**
tuberculosis or other infection?   No ◯

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	XRPREF	$2		1 = Screening 2 = Prior to screening		XRPREF
2	XRDAT	dd/MMM/yyyy				XRDAT
3	XRRES	$2		1 = Normal 2 = Abnormal, clinically significant 3 = Abnormal, not clinically significant		XRRES
4	XRINFEC	$2		Y = Yes N = No		XRINFEC

Was the participant fasting prior to sample collection?   Yes◯ ①
No◯
Unknown◯

Indicate which samples were collected

Clinical Chemistry _____ ③

Hematology _____ ④

Urinalysis _____ ⑤

No samples were collected _____ ⑥

If No samples were collected, please provide reason _____ ⑦

Date of Sample Collection (DD/MMM/YYYY) _____ ⑧

Time of Sample Collection (24 HR) _____ ⑨

Was the sample sent to the Laboratory?

Clinical Chemistry   Yes◯ ⑪
No◯
NA◯

If No, please provide reason _____ ⑫

Hematology   Yes ◯ **13**
                                                                No ◯
                                                                NA ◯

If No, please provide reason   _____ **14**

Urinalysis   Yes ◯ **15**
                                                                No ◯
                                                                NA ◯

If No, please provide reason   _____ **16**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBFAST	$2		Y = Yes N = No UN = Unknown		LBFAST
3	LBCHEM	1				LBCHEM
4	LBHEM	1				LBHEM
5	LBURIN	1				LBURIN
6	LBNONE	1				LBNONE
7	LBSPEC1	$200				LBSPEC1
8	LBDATE	dd/MMM/yyyy				LBDATE
9	LBTIM	HH:nn				LBTIM
11	LBCMYN	$2		Y = Yes N = No NA = NA		LBCMYN
12	LBREAS3	$200				LBREAS3
13	LBHMYN	$2		Y = Yes		LBHMYN

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			N = No NA = NA		
(14) LBREAS4	$200				LBREAS4
(15) LBURYN	$2		Y = Yes N = No NA = NA		LBURYN
(16) LBREAS5	$200				LBREAS5

Was a sample collected?   Yes ◯ ①
                                                                 No ◯

If No, please provide reason   _____ ②

Date of Sample Collection (DD/MMM/YYYY)   _____ ③

Time of Sample Collection (24 HR)   _____ ④

Was the sample sent to the Laboratory?   Yes ◯ ⑤
                                                                 No ◯

If No, please provide the reason   _____ ⑥

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yyyy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ◯ ①
                                                            No ◯

If No, please provide reason   _____ ②

Date of Sample Collection (DD/MMM/YYYY)   _____ ③

Time of Sample Collection (24 HR)   _____ ④

Was the sample sent to the Laboratory?   Yes ◯ ⑤
                                                            No ◯

If No, please provide reason   _____ ⑥

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yyyy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ◯ **①**
                                                            No ◯

If No, please provide reason   _____ **②**

Date of Sample Collection (DD/MMM/YYYY)   _____ **③**

Time of Sample Collection (24 HR)   _____ **④**

Was the sample sent to the Laboratory?   Yes ◯ **⑤**
                                                            No ◯

If No, please provide reason   _____ **⑥**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(1) LBYN	$1		Y = Yes N = No		LBYN
(2) LBREAS	$200				LBREAS
(3) LBDATE	dd/MMM/yyyy				LBDATE
(4) LBTIM	HH:nn				LBTIM
(5) LBSENT	$1		Y = Yes N = No		LBSENT
(6) LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ◯ ①
                                                                 No ◯

If No, please provide reason   _____ ②

Date of Sample Collection (DD/MMM/YYYY)   _____ ③

Time of Sample Collection (24 HR)   _____ ④

Was the sample sent to the Laboratory?   Yes ◯ ⑤
                                                                 No ◯

If No, please provide the reason   _____ ⑥

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PREGYN	$1		Y = Yes N = No		PREGYN
② PGREAS	$200				PGREAS
③ PREGDAT	dd/MMM/yy yy				PREGDAT
④ PREGTIM	HH:nn				PREGTIM
⑤ PGSAMP	$2		Y = Yes N = No		PGSAMP
⑥ PGREAS2	$200				PGREAS2

Was a sample collected?   Yes ◯ ①
                                                        No ◯

If No, please provide reason   _____ ②

Date of sample Collection (DD/MMM/YYYY) _____ ③

Time of sample Collection (24 Hr)   _____ ④

Was the sample sent to the Laboratory?   Yes ◯ ⑤
                                                        No ◯

If No, please provide the reason   _____ ⑥

Note: FSH test is to be performed to confirm postmenopausal status in females who are amenorrheic for at least 12
consecutive months.

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yy yy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ⃝ **①**
                                                               No ⃝

If No, please provide reason   _____ **②**

Date of sample Collection (DD/MMM/YYYY)   _____ **③**

Time of sample Collection (24 Hr)   _____ **④**

Was the sample sent to the Laboratory?   Yes ⃝ **⑤**
                                                               No ⃝

If No, please provide the reason   _____ **⑥**

Note: Estradiol test is to be performed to confirm postmenopausal status in females who are amenorrheic for
at least 12 consecutive months.

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yy yy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ◯ ①
                                                            No ◯

If No, please provide reason   _____ ②

Date of Sample Collection (DD/MMM/YYYY)   _____ ③

Time of Sample Collection (24 HR)   _____ ④

Was the sample sent to the Laboratory?   Yes ◯ ⑤
                                                            No ◯

If No, please provide reason   _____ ⑥

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBYN	$1		Y = Yes N = No		LBYN
② LBREAS	$200				LBREAS
③ LBDATE	dd/MMM/yyyy				LBDATE
④ LBTIM	HH:nn				LBTIM
⑤ LBSENT	$1		Y = Yes N = No		LBSENT
⑥ LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ⃝ **①**
                                                            No ⃝

If No, please provide reason   _____ **②**

Date of Sample Collection (DD/MMM/YYYY)   _____ **③**

Time of Sample Collection (24 HR)   _____ **④**

Was the sample sent to the Laboratory?   Yes ⃝ **⑤**
                                                            No ⃝

If No, please provide reason   _____ **⑥**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yy yy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ◯ **①**
                                                            No ◯

If No, please provide reason   _____ **②**

Date of Sample Collection (DD/MMM/YYYY) _____ **③**

Time of Sample Collection (24 HR)   _____ **④**

Was the sample sent to the Laboratory?   Yes ◯ **⑤**
                                                            No ◯

If No, please provide reason   _____ **⑥**

Derived Date and Time   _____ **⑦**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yyyy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2
7	LBDTTIM	dd/MMM/yyyy HH:nn				LBDTTIM

Will the participant have a Screening Visit?   Yes◯**①**
                                                                No◯

If No, complete only the Demographics form in the Screening Visit.

If No, please select reason(s) why participant will not continue to the Screening Visit:

Results of Tuberculosis Test (IGRA)   _____**④**

Results of TSI Test   _____**⑤**

Other   _____**⑥**

If Other, please specify: _____**⑦**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① CSPSYN	$1		Y = Yes N = No		CSPSYN
④ CSPSIGRA	1				CSPSIGRA
⑤ CSPSTSI	1				CSPSTSI
⑥ CSPSOTH	1				CSPSOTH
⑦ CSPSOSP	$200				CSPSOSP

Was the assessment performed?   Yes ◯ ①
No ◯

If No, specify reason _____ ②

Date of assessment (DD/MMM/YYYY) _____ ③

Height   **cm** ◯ ④
in ◯

Weight   **kg** ◯ ⑤
lb ◯

BMI (kg/m2)   ⑥
[auto calculation] (Derived from Height and Weight)
_____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	HWYN	$1		Y = Yes N = No		HWYN
2	HWREAS	$200				HWREAS
3	HWDT	dd/MMM/yy yy				HWDT
4	HEIGHT	5.2	cm = cm in = in			HEIGHT
5	WEIGHT	5.2	kg = kg lb = lb			WEIGHT
6	BMI	5.2				BMI

Was vital signs assessment performed?   Yes◯ **1**
                                                No◯

If no, reason not performed   _____ **2**

Date of assessment (DD/MMM/YYYY)   _____ **3**

Time of assessment (24 HR)   _____ **4**

Heart Rate (beats/min)   _____ **5**

Systolic blood pressure (mmHg)   _____ **6**

Diastolic blood pressure (mmHg)   _____ **7**

Respiratory rate (breaths/min)   _____ **8**

Temperature   _____ **9**

Temperature unit   F◯ **10**
                         C◯

Method of temperature measurement   Oral◯ **11**
                                       Tympanic◯
                                          Other◯

If Other, please specify   _____ **12**

Vital Signs Body Position?

Sitting ⃝ **13**
Standing ⃝
Supine ⃝

Please select which arm was used for Measurements?

Left ⃝ **14**
Right ⃝

BP and HR measurements should be conducted in the sitting position (with the participant's arm supported at the level
of the heart) and with the arm unconstrained by clothing. If the participant is in a different position (e.g., standing or lying
down), then this should be noted in the eCRF.

Please report ongoing clinically significant abnormalities during screening on the Medical History page.
If any new clinically significant abnormality began or worsened after the administration of study intervention until the
safety follow-up period, please report it on the Adverse
Events page.

Vital signs are to be obtained before the nominal time of the blood collection.

Derived Date and Time _____ **16**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VS1YN	$1		Y = Yes N = No		VS1YN
②	VS1REAS	$200				VS1REAS
③	VS1DAT	dd/MMM/yyyy				VS1DAT
④	VS1TIM	HH:nn				VS1TIM
⑤	VS1HR	3				VS1HR
⑥	VS1SYSBP	3				VS1SYSBP
⑦	VS1DIABP	3				VS1DIABP
⑧	VS1RR	3				VS1RR
⑨	VS1TEMP	4.1				VS1TEMP
⑩	VS1UNIT	$1		1 = F 2 = C		VS1UNIT
⑪	VS1METH	$2		1 = Oral 2 = Tympanic 99 = Other		VS1METH

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑫ VS1METHO	$200				VS1METHO
⑬ VS1BDPS	$1		1 = Sitting 2 = Standing 3 = Supine		VS1BDPS
⑭ VS1ARM	$1		1 = Left 2 = Right		VS1ARM
⑯ VS1DATTIM	dd/MMM/yyyy HH:nn				VS1DATTIM

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: VITAL SIGNS (VISIT WITH STUDY TREATMENT)
Generated On: 30 May 2025 22:31:51 (GMT)

Were Vital Signs Performed?   Yes ◯ **①**
                                                              No ◯

If No, please provide reason   _____ **②**

Date of assessment (DD/MMM/YYYY)   _____ **③**

Timepoint   Pre-Dose ◯ **④**
                                                Post Dose (1) ◯
                                                Post Dose (2) ◯

Not
done   _____ **⑤**

Time of
assessment
(24 HR)   _____ **⑥**

Heart rate
(beats/min)   _____ **⑦**

Systolic
Blood
Pressure
(mmHg)   _____ **⑧**

Diastolic Blood Pressure(mmHg)   _____ **⑨**

Respiratory
rate (breaths/
min)   _____ **⑩**

Temperature _____ (11)

Temperature Units   F ◯ (12)
                                           C ◯

Method of temperature measurement   Oral ◯ (13)
                                   Tympanic ◯
                                      Other ◯

If Other,
please specify _____ (14)

Vital Signs Body   Sitting ◯ (15)
Position?   Standing ◯
                                        Supine ◯

Please select which arm was used for   Left ◯ (16)
Measurements?   Right ◯

BP and HR measurements should be conducted in the sitting position (with the participant's arm supported at the level of the heart) and with the arm unconstrained by clothing. If the participant is in a different position (e.g., standing or lying down), then this should be noted in the eCRF.

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Date and Time Derivation _____ (19)

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	VSYN	$1		Y = Yes N = No		VSYN
2	VSREAS	$200				VSREAS
3	VSDAT	dd/MMM/yyyy				VSDAT
4	VSTPT	$1		1 = Pre-Dose 2 = Post Dose (1) 3 = Post Dose (2)	1: Pre-Dose 2: Post Dose (1) 3: Post Dose (2)	VSTPT
5	VSND	1				VSND
6	VSTIM	HH:nn				VSTIM
7	VSHR	3				VSHR
8	VSSYSBP	3				VSSYSBP
9	VSDIABP	3				VSDIABP
10	VSRR	3				VSRR
11	VSTEMP	4.1				VSTEMP

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(12) VSUNIT	$1		1 = F 2 = C		VSUNIT
(13) VSMETH	$2		1 = Oral 2 = Tympanic 99 = Other		VSMETH
(14) VSOTH	$200				VSOTH
(15) VSBDPS	$1		1 = Sitting 2 = Standing 3 = Supine		VSBDPS
(16) VSARM	$1		1 = Left 2 = Right		VSARM
(19) VSDATTIM	dd/MMM/yyyy HH:nn				VSDATTIM

Was physical examination performed?   Yes ◯ **①**
                                        No ◯

If No, please provide reason   _____ **②**

Date of physical examination (DD/MMM/YYYY)   _____ **③**

Body System
Examined   General appearance ◯ **④**
            Skin ◯
            Head, eyes, ears, nose, ◯
            and throat, including
            mouth
            Heart ◯
            Lungs/chest ◯
            Abdomen ◯
            Extremities ◯
            Neurologic ◯
            Back ◯
            Lymph Nodes ◯
            Other ◯

Other Body System,   **⑤**
Specify   _____

Examination   Normal ◯ **⑥**
Result   Abnormal NCS ◯
          Abnormal CS ◯

Examination Findings   **⑦**
(If Abnormal)   _____

Not
Done   ⑧

Reason for not done   ⑨

If any new clinically significant abnormality began or worsened please report it on the
Adverse Event page.

Last Saved   ⑪

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PEYN	$1		Y = Yes N = No		PEYN
② PENO	$200				PENO
③ PEDAT	dd/MMM/yyyy				PEDAT
④ PETEST	$2		1 = General appearance 2 = Skin 3 = Head, eyes, ears, nose, and throat, including mouth 4 = Heart 5 = Lungs/chest 6 = Abdomen 7 = Extremities 8 = Neurologic 9 = Back 10 = Lymph Nodes 99 = Other	1: General appearance 2: Skin 3: Head, eyes, ears, nose, and throat, including mouth 4: Heart 5: Lungs/chest 6: Abdomen 7: Extremities 8: Neurologic 9: Back 10: Lymph Nodes 11: Other 12: Other 13: Other 14: Other 15: Other	PETEST

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(5) PEOTH	$200				PEOTH
(6) PERES	$1		1 = Normal 2 = Abnormal NCS 3 = Abnormal CS		PERES
(7) PEDESC	$200				PEDESC
(8) PEND	1				PEND
(9) PEREAS	$200				PEREAS
(11) H_NOW	dd MMM yyyy HH:nn:ss				H_NOW

Was a 12-lead ECG performed? Yes ◯ **1**
No ◯

If No, please provide reason _____ **2**

Date of assessment (DD/MMM/YYYY) _____ **3**

Time of assessment (24 HR) _____ **4**

Was the 12-Lead ECG transmitted to the Reading center? Yes ◯ **5**
No ◯

If No, please provide reason _____ **6**

Note: All scheduled ECGs will be performed after the participant has rested quietly for at least 10 minutes in a supine position.

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1 EGPERF	$1		Y = Yes N = No		EGPERF
2 EGREAS	$200				EGREAS
3 EGDT	dd/MMM/yyyy				EGDT
4 EGTIM	HH:nn				EGTIM
5 EGTRANS	$1		Y = Yes N = No		EGTRANS
6 EGREAS1	$200				EGREAS1

Were all components of the exam completed?   Yes ◯ ①
                                                      No ◯

If no, provide reason   _____ ②

Date of Assessment (DD/MMM/YYYY)   _____ ③

Time of Assessment (24 HR)   _____ ④

BCVA

Unit of Measurement   Feet ◯ ⑥
                               Meters ◯

Snellen Acuity Numerator - OD   _____ ⑦

Snellen Acuity Denominator - OD   _____ ⑧

For BCVA less than 20/400 or equivalent for OD, please
specify. See Study Operations Manual for more details.   _____ ⑨

Snellen Acuity Numerator - OS   _____ ⑩

Snellen Acuity Denominator - OS   _____ ⑪

For BCVA less than 20/400 or equivalent for OS, please
specify. See Study Operations Manual for more details.   _____ ⑫

REFRACTION - RIGHT EYE (OD)

Not Assessed ⑭

Sphere + ○ ⑮
- ○
PL ○

⑯

Cylinder + ○ ⑰
- ○

⑱

N/A ⑲

Axis (Degrees) - OD ⑳

N/A ㉑

REFRACTION - LEFT EYE (OS)

Not Assessed ㉓

Sphere + ○ ㉔
- ○
PL ○

㉕

Cylinder   + ◯ **26**
                                                            - ◯

_____ **27**

  N/A   _____ **28**

Axis (Degrees) - OS   _____ **29**

  N/A   _____ **30**

EXTERNAL

Eyelids

Not Assessed   _____ **33**

Eyelid Swelling that is considered to be due to active   0=Absent ◯ **34**
(inflammatory phase) TED   1=Present ◯
(CAS) - OD

Eyelid erythema (CAS) - OD   0=Absent ◯ **35**
                                                           1=Present ◯

Palpebral aperture (mm) - OD-OBSOLETE   _____ **36**

Palpebral aperture (mm) - OD (Derived)   _____ **37**

Upper lid retraction (MRD1) (mm) - OD   _____ **38**

Lower lid retraction (MRD2) (mm) – OD _____ (39)

Eyelid Swelling that is considered to be due to active (inflammatory phase) TED (CAS) - OS

0=Absent ◯ (40)
1=Present ◯

Eyelid erythema (CAS) - OS

0=Absent ◯ (41)
1=Present ◯

Palpebral aperture (mm) - OS-OBSOLETE _____ (42)

Palpebral aperture (mm) - OS (Derived) _____ (43)

Upper lid retraction (MRD1) (mm) - OS _____ (44)

Lower lid retraction (MRD2) (mm) – OS _____ (45)

Proptosis (mm)

Not Assessed _____ (47)

Exophthalmometer reading (Hertel value (mm)) - OD _____ (48)

Exophthalmometer reading (Hertel value (mm)) - OS _____ (49)

Distance between lateral rims (mm) _____ (50)

Exophthalmometer ID (Hertel exophthalmometer identifier) _____ (51)

Evaluator Initials _____ 53

Monocular Ductions (Degrees)

Not Assessed _____ 54

Adduction - OD _____ 55

Abduction - OD _____ 56

Elevation (Supraduction) OD _____ 57

Depression (Infraduction) for OD _____ 58

Adduction - OS _____ 59

Abduction - OS _____ 60

Elevation (Supraduction) OS _____ 61

Depression (Infraduction) for OS _____ 62

Orbital Pain

Not Assessed _____ 64

Spontaneous orbital pain (CAS) - OD   0=Absent ◯ 65
1=Present ◯

Gaze evoked orbital pain (CAS) - OD

0=Absent ◯ **66**
1=Present ◯

Spontaneous orbital pain (CAS) - OS

0=Absent ◯ **67**
1=Present ◯

Gaze evoked orbital pain (CAS) - OS

0=Absent ◯ **68**
1=Present ◯

Ocular Alignment

Diplopia Score (Gorman)

Was Diplopia score done ?

Yes ◯ **70**
No ◯

Please select Diplopia score

No Diplopia (absent) (0) ◯ **71**
Diplopia when participant is ◯
tired or awakening
(intermittent) (1)
Diplopia at extremes of ◯
gaze (inconstant) (2)
Continuous Diplopia in the ◯
primary or reading position
(constant) (3)

Modified Gorman Diplopia Score

Was Modified Gorman Scale done?

Yes ◯ **73**
No ◯

NA ◯

Straight Ahead	No diplopia ◯ 74
	Intermittent diplopia ◯
	Constant diplopia ◯

Left Gaze	No diplopia ◯ 75
	Intermittent diplopia ◯
	Constant diplopia ◯

Right Gaze	No diplopia ◯ 76
	Intermittent diplopia ◯
	Constant diplopia ◯

Upward Gaze	No diplopia ◯ 77
	Intermittent diplopia ◯
	Constant diplopia ◯

Downward Gaze	No diplopia ◯ 78
	Intermittent diplopia ◯
	Constant diplopia ◯

Observed

Not Assessed _____ 80

| Esotropia - OD | Yes ◯ 81 |
| | No ◯ |

Exotropia - OD   Yes ◯ **82**
                                                        No ◯

Hypotropia - OD   Yes ◯ **83**
                                                        No ◯

Hypertropia - OD   Yes ◯ **84**
                                                        No ◯

Esotropia - OS   Yes ◯ **85**
                                                        No ◯

Exotropia - OS   Yes ◯ **86**
                                                        No ◯

Hypotropia - OS   Yes ◯ **87**
                                                        No ◯

Hypertropia - OS   Yes ◯ **88**
                                                        No ◯

Color Vision (Number of correct plates out of 38)

Not Assessed   _____ **90**

Right Eye (OD)   _____ **91**

Left Eye (OS) _____ **97**

Pupils

Not Assessed _____ **94**

Is Afferent Pupillary Defect (APD) present? - OD
Yes ⬜ **95**
No ⬜

Are the pupils reactive to light? - OD
Yes ⬜ **96**
No ⬜

Is Afferent Pupillary Defect (APD) present? - OS
Yes ⬜ **97**
No ⬜

Are the pupils reactive to light? - OS
Yes ⬜ **98**
No ⬜

Confrontational Visual fields

Is there a restriction in the visual field?

Not Assessed _____ **100**

Nasal - OD
Yes ⬜ **101**
No ⬜

Temporal - OD

Yes ◯ **102**
No ◯

Superior - OD

Yes ◯ **103**
No ◯

Inferior - OD

Yes ◯ **104**
No ◯

Superior Nasal - OD

Yes ◯ **105**
No ◯

Inferior Nasal - OD

Yes ◯ **106**
No ◯

Superior Temporal - OD

Yes ◯ **107**
No ◯

Inferior Temporal - OD

Yes ◯ **108**
No ◯

Nasal - OS

Yes ◯ **109**
No ◯

Temporal - OS

Yes ◯ **110**
No ◯

Superior - OS

Yes ⬜ 111
No ⬜

Inferior - OS

Yes ⬜ 112
No ⬜

Superior Nasal - OS

Yes ⬜ 113
No ⬜

Inferior Nasal - OS

Yes ⬜ 114
No ⬜

Superior Temporal - OS

Yes ⬜ 115
No ⬜

Inferior Temporal - OS

Yes ⬜ 116
No ⬜

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	OPYN	$2		Y = Yes N = No		OPYN
2	OPREAS	$200				OPREAS
3	OPDAT	dd/MMM/yyyy				OPDAT
4	OPTIM	HH:nn				OPTIM
6	OPSUNIT	$1		1 = Feet 2 = Meters		OPSUNIT
7	OPSNOD1	2				OPSNOD1
8	OPSNOD2	7.2				OPSNOD2
9	OPSBCVA	$200				OPSBCVA
10	OPSNOS1	2				OPSNOS1
11	OPSNOS2	7.2				OPSNOS2
12	OPSBCVA1	$200				OPSBCVA1
14	RREODNA	1				RREODNA

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15	OPSHOD	$1		1 = + 2 = - 3 = PL		OPSHOD
16	OPSHODCO	4.2				OPSHODCO
17	OPCYOD	$1		1 = + 2 = -		OPCYOD
18	OPCYODCO	4.2				OPCYODCO
19	OPXNA3	1				OPXNA3
20	OPAXISOD	5				OPAXISOD
21	OPXNA	1				OPXNA
23	RLEOSNA	1				RLEOSNA
24	OPSHOS	$1		1 = + 2 = - 3 = PL		OPSHOS
25	OPSHOSCO	4.2				OPSHOSCO
26	OPCYOS	$1		1 = + 2 = -		OPCYOS

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
27	OPCYOSCO	4.2				OPCYOSCO
28	OPXNA4	1				OPXNA4
29	OPAXISOS	5				OPAXISOS
30	OPXNA2	1				OPXNA2
33	EYELDNA	1				EYELDNA
34	OPSWOD	$1		1 = 0=Absent 2 = 1=Present		OPSWOD
35	OPETHOD	$1		1 = 0=Absent 2 = 1=Present		OPETHOD
36	OPPALOD	3.1				OPPALOD
37	Z_OPPALOD	3.1				Z_OPPALOD
38	OPLIDOD	3.1				OPLIDOD
39	OPLIDOD1	3.1				OPLIDOD1

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(40) OPSWOS	$1		1 = 0=Absent 2 = 1=Present		OPSWOS
(41) OPETHOS	$1		1 = 0=Absent 2 = 1=Present		OPETHOS
(42) OPPALOS	3.1				OPPALOS
(43) Z_OPPALOS	3.1				Z_OPPALOS
(44) OPLIDOS	3.1				OPLIDOS
(45) OPLIDOS1	3.1				OPLIDOS1
(47) PROPNA	1				PROPNA
(48) OPEXOD	3.1				OPEXOD
(49) OPEXOS	3.1				OPEXOS
(50) OPINT	4.1				OPINT
(51) OPEX	$10				OPEX

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
52 OPEV	$5				OPEV
54 MDNA	1				MDNA
55 OPADOD	5.2				OPADOD
56 OPBOD	5.2				OPBOD
57 OPDEGOD	5.2				OPDEGOD
58 OPINFROD	5.2				OPINFROD
59 OPADOS	5.2				OPADOS
60 OPBOS	5.2				OPBOS
61 OPDEGOS	5.2				OPDEGOS
62 OPINFROS	5.2				OPINFROS
64 OBPNA	1				OBPNA
65 OPSPONOD	$1		1 = 0=Absent 2 = 1=Present		OPSPONOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
66 OPGZOD	$1		1 = 0=Absent 2 = 1=Present		OPGZOD
67 OPSPONOS	$1		1 = 0=Absent 2 = 1=Present		OPSPONOS
68 OPGZOS	$1		1 = 0=Absent 2 = 1=Present		OPGZOS
70 OPDIPSC	$1		Y = Yes N = No		OPDIPSC
71 OPDIP	$1		1 = No Diplopia (absent) (0) 2 = Diplopia when participant is tired or awakening (intermittent) (1)		OPDIP

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Diplopia at extremes of gaze (inconstant) (2) 4 = Continuous Diplopia in the primary or reading position (constant) (3)		
73 OPMGSYN	$2		Y = Yes N = No NA = NA		OPMGSYN
74 MGSSA	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSSA
75 MGSLG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSLG

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
76	MGSRG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSRG
77	MGSUG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSUG
78	MGSDG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSDG
80	OBSVNA	1				OBSVNA
81	OPESOD	$1		Y = Yes N = No		OPESOD
82	OPXOOD	$1		Y = Yes		OPXOOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			N = No		
83 OPHYOD	$1		Y = Yes N = No		OPHYOD
84 OPPIAOD	$1		Y = Yes N = No		OPPIAOD
85 OPESOS	$1		Y = Yes N = No		OPESOS
86 OPXOOS	$1		Y = Yes N = No		OPXOOS
87 OPHYOS	$1		Y = Yes N = No		OPHYOS
88 OPPIAOS	$1		Y = Yes N = No		OPPIAOS
90 CVNA	1				CVNA
91 OPCVOD	2				OPCVOD
92 OPCVOS	2				OPCVOS
94 PUPNA	1				PUPNA

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
95 OPAPDOD	$1		Y = Yes N = No		OPAPDOD
96 OPLGHOD	$1		Y = Yes N = No		OPLGHOD
97 OPAPDOS	$1		Y = Yes N = No		OPAPDOS
98 OPLGHOS	$1		Y = Yes N = No		OPLGHOS
100 CONFNA	1				CONFNA
101 OPNAOD	$1		Y = Yes N = No		OPNAOD
102 OPTEMOD	$1		Y = Yes N = No		OPTEMOD
103 OPSSOD	$1		Y = Yes N = No		OPSSOD
104 OPSIOD	$1		Y = Yes N = No		OPSIOD
105 OPSNOD	$1		Y = Yes N = No		OPSNOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
106 OPINOD	$1		Y = Yes N = No		OPINOD
107 OPSTOD	$1		Y = Yes N = No		OPSTOD
108 POITOD	$1		Y = Yes N = No		POITOD
109 OPNAOS	$1		Y = Yes N = No		OPNAOS
110 OPTEMOS	$1		Y = Yes N = No		OPTEMOS
111 OPSSOS	$1		Y = Yes N = No		OPSSOS
112 OPSIOS	$1		Y = Yes N = No		OPSIOS
113 OPSNOS	$1		Y = Yes N = No		OPSNOS
114 OPINOS	$1		Y = Yes N = No		OPINOS
115 OPSTOS	$1		Y = Yes N = No		OPSTOS

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(116) POITOS	$1		Y = Yes N = No		POITOS

Were all components of the exam completed? Yes ◯ ①
No ◯

If no, provide reason _____ ②

Date of Assessment (DD/MMM/YYYY) _____ ③

Time of Assessment (24 HR) _____ ④

Conjunctiva

Not Assessed _____ ⑥

Conjunctival redness that is considered to be due to active (inflammatory phase) TED (CAS) - OD 0=Absent ◯ ⑦
1=Present ◯

Chemosis (CAS) - OD 0=Absent ◯ ⑧
1=Present ◯

If there are other abnormalities, please specify - OD _____ ⑨

Conjunctival redness that is considered to be due to active (inflammatory phase) TED (CAS) - OS 0=Absent ◯ ⑩
1=Present ◯

Chemosis (CAS) - OS 0=Absent ◯ ⑪
1=Present ◯

If there are other abnormalities, please specify - OS _____ ⑫

Plica

Not Assessed   (14)

Inflammation of caruncle or plica (CAS) - OD   0=Absent ◯ (15)
                                                       1=Present ◯

If there are other abnormalities, please specify - OD   (16)

Inflammation of caruncle or plica (CAS) - OS   0=Absent ◯ (17)
                                                       1=Present ◯

If there are other abnormalities, please specify - OS   (18)

Cornea

Not Assessed   (20)

Clear - OD   Yes ◯ (21)
                                                               No ◯

Superficial Punctate Keratitis - OD   Yes ◯ (22)
                                                               No ◯

Ulcer - OD   Yes ◯ (23)
                                                               No ◯

If there are other abnormalities, please specify - OD   (24)

Clear - OS   Yes◯ **25**
                                                        No◯

Superficial Punctate Keratitis - OS   Yes◯ **26**
                                                        No◯

Ulcer - OS   Yes◯ **27**
                                                        No◯

If there are other abnormalities, please specify - OS   _____ **28**

Anterior Chamber

Not Assessed   _____ **30**

Clear - OD   Yes◯ **31**
                                                        No◯

Deep - OD   Yes◯ **32**
                                                        No◯

If abnormal, please specify - OD   _____ **33**

Clear - OS   Yes◯ **34**
                                                        No◯

Deep - OS   Yes◯ **35**

No ◯

If abnormal, please specify - OS _____ **36**

Iris

Not Assessed _____ **38**

Normal - OD   Yes ◯ **39**
                                                       No ◯

If Abnormal, please specify - OD _____ **40**

Normal - OS   Yes ◯ **41**
                                                       No ◯

If Abnormal, please specify - OS _____ **42**

Lens

Not Assessed _____ **44**

Lens - OD   Normal phakic ◯ **45**
                                           Abnormal phakic ◯
                                             Pseudophakic ◯
                                                  Aphakic ◯

If Abnormal phakic, check all that apply - OD (Lens)

Cataract nuclear _____ **47**

Cataract cortical _____ **48**

Cataract posterior subcapsular _____ **49**

Other _____ **50**

If Other, please describe _____ **51**

If Abnormal phakic, has there been any progression of cataract since screening? - OD

Yes ◯ **52**
No ◯

If Yes, please describe _____ **53**

If Pseudophakic, please select - OD

Posterior chamber lens ◯ **54**
Anterior chamber lens ◯
Other ◯

If Other, please specify - OD (Pseudophakic) _____ **55**

Lens - OS

Normal phakic ◯ **56**
Abnormal phakic ◯
Pseudophakic ◯
Aphakic ◯

If Abnormal phakic, check all that apply - OS

Cataract nuclear _____ (58)

Cataract cortical _____ (59)

Cataract posterior subcapsular _____ (60)

Other _____ (61)

If Other, please describe _____ (62)

If Abnormal phakic, has there been any progression of cataract since screening? - OS   Yes ⬭ (63)   No ⬭

If Yes, please describe _____ (64)

If Pseudophakic, please select - OS   Posterior chamber lens ⬭ (65)   Anterior chamber lens ⬭   Other ⬭

If Other, please specify _____ (66)

IOP

Not Assessed _____ (68)

mmHg - OD _____ (69)

mmHg - OS _____ (70)

Method

Tonopen ◯ **71**
Goldmann tonometry ◯
Other ◯

If Other, please specify _____ **72**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① OPYN	$2		Y = Yes N = No		OPYN
② OPREAS	$200				OPREAS
③ OPDAT	dd/MMM/yyyy				OPDAT
④ OPTIM	HH:nn				OPTIM
⑥ OPCONA	1				OPCONA
⑦ OPCONOD	$1		1 = 0=Absent 2 = 1=Present		OPCONOD
⑧ OPCHOD	$1		1 = 0=Absent 2 = 1=Present		OPCHOD
⑨ OPSPEC1	$200				OPSPEC1
⑩ OPCONOS	$1		1 = 0=Absent 2 = 1=Present		OPCONOS

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(11) OPCHOS	$1		1 = 0=Absent 2 = 1=Present		OPCHOS
(12) OPSPECOS	$200				OPSPECOS
(14) OPPLINA	1				OPPLINA
(15) OPPLIOD	$1		1 = 0=Absent 2 = 1=Present		OPPLIOD
(16) OPSPEC2	$200				OPSPEC2
(17) OPPLIOS	$1		1 = 0=Absent 2 = 1=Present		OPPLIOS
(18) OPSPECO	$200				OPSPECO
(20) OPCLODNA	1				OPCLODNA
(21) OPCLOD	$1		Y = Yes N = No		OPCLOD
(22) OPSUOD	$1		Y = Yes		OPSUOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			N = No		
㉓ OPULOD	$1		Y = Yes N = No		OPULOD
㉔ OPSPEC3	$200				OPSPEC3
㉕ OPCLOS	$1		Y = Yes N = No		OPCLOS
㉖ OPSUOS	$1		Y = Yes N = No		OPSUOS
㉗ OPULOS	$1		Y = Yes N = No		OPULOS
㉘ OPSPEC9	$200				OPSPEC9
㉚ OPCODNA	1				OPCODNA
㉛ OPCOD	$1		Y = Yes N = No		OPCOD
㉜ OPDOD	$1		Y = Yes N = No		OPDOD
㉝ OPSPEC4	$200				OPSPEC4

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
34 OPCOS	$1		Y = Yes N = No		OPCOS
35 OPDOS	$1		Y = Yes N = No		OPDOS
36 OPSPEC11	$200				OPSPEC11
38 OPIODNA	1				OPIODNA
39 OPIOD	$1		Y = Yes N = No		OPIOD
40 OPSPEC5	$200				OPSPEC5
41 OPIOS	$1		Y = Yes N = No		OPIOS
42 OPSPEC10	$200				OPSPEC10
44 OPHODNA	1				OPHODNA
45 OPLENSOD	$1		1 = Normal phakic 2 = Abnormal phakic		OPLENSOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Pseudophakic 4 = Aphakic		
47 OPCATOD	1				OPCATOD
48 OPCCOD	1				OPCCOD
49 OPPSOD	1				OPPSOD
50 OPOTH2	1				OPOTH2
51 OPSPEC14	$200				OPSPEC14
52 OPKOD	$1		Y = Yes N = No		OPKOD
53 OPSPEC6	$200				OPSPEC6
54 OPPOOD	$1		1 = Posterior chamber lens 2 = Anterior chamber lens		OPPOOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Other		
55 OPSPEC12	$200				OPSPEC12
56 OPLENSOS	$1		1 = Normal phakic 2 = Abnormal phakic 3 = Pseudophakic 4 = Aphakic		OPLENSOS
58 OPCATOS	1				OPCATOS
59 OPCCOS	1				OPCCOS
60 OPPSOS	1				OPPSOS
61 OPOTH	1				OPOTH
62 OPSPEC13	$200				OPSPEC13
63 OPKKOS	$1		Y = Yes N = No		OPKKOS
64 OPSPEC7	$200				OPSPEC7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
65	OPPOOS	$1		1 = Posterior chamber lens 2 = Anterior chamber lens 3 = Other		OPPOOS
66	OPSPEC8	$200				OPSPEC8
68	OPMGNA	1				OPMGNA
69	OPMMGOD	3.1				OPMMGOD
70	OPMMGOS	3.1				OPMMGOS
71	OPMETOS	$1		1 = Tonopen 2 = Goldmann tonometry 3 = Other		OPMETOS
72	OPMETOTH	$200				OPMETOTH

Were all components of the exam completed? Yes◯ **1**
No◯

If no, provide reason _____ **2**

Date performed (DD/MMM/YYYY) _____ **3**

Time of Assessment (24 HR) _____ **4**

Vitreous

Not Assessed _____ **6**

OD Normal◯ **7**
Abnormal◯

If abnormal, please specify - OD _____ **8**

OS Normal◯ **9**
Abnormal◯

If abnormal, please specify - OS _____ **10**

Optic Nerve

Not Assessed _____ **12**

Optic Nerve Normal - OD Yes◯ **13**

No ◯

Optic Nerve Pallor - OD   Yes ◯ **14**
                                                           No ◯

Optic Nerve Swelling - OD   Yes ◯ **15**
                                                           No ◯

If there are other abnormalities, please specify - OD   _____ **16**

Optic Nerve Cup to Disc (C/D) - OD   _____ **17**

Optic Nerve Normal - OS   Yes ◯ **18**
                                                           No ◯

Optic Nerve Pallor - OS   Yes ◯ **19**
                                                           No ◯

Optic Nerve Swelling - OS   Yes ◯ **20**
                                                           No ◯

If there are other abnormalities, please specify - OS   _____ **21**

Optic Nerve Cup to Disc (C/D) - OS   _____ **22**

Macula

Not Assessed _____ **24**

OD Normal ◯ **25**
Abnormal ◯

If abnormal, please specify - OD _____ **26**

OS Normal ◯ **27**
Abnormal ◯

If abnormal, please specify - OS _____ **28**

Retinal Vessels

Not Assessed _____ **30**

OD Normal ◯ **31**
Abnormal ◯

If abnormal, please specify - OD _____ **32**

OS Normal ◯ **33**
Abnormal ◯

If abnormal, please specify - OS _____ **34**

Peripheral Retina

Not Assessed _____ **36**

OD Normal ⟡ **37**
Abnormal ⟡

If abnormal, please specify - OD _____ **38**

OS Normal ⟡ **39**
Abnormal ⟡

If abnormal, please specify - OS _____ **40**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	OPYN	$2		Y = Yes N = No		OPYN
2	OPREAS	$200				OPREAS
3	OPDAT	dd/MMM/yyyy				OPDAT
4	OPTIM	HH:nn				OPTIM
6	OPODNA	1				OPODNA
7	OPOD	$1		1 = Normal 2 = Abnormal		OPOD
8	OPODSP	$200				OPODSP
9	OPOS	$1		1 = Normal 2 = Abnormal		OPOS
10	OPOSSP	$200				OPOSSP
12	OPNODNA	1				OPNODNA
13	OPNOD	$1		Y = Yes N = No		OPNOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(14) OPPOD	$1		Y = Yes N = No		OPPOD
(15) OPSOD	$1		Y = Yes N = No		OPSOD
(16) OPNSPOD	$200				OPNSPOD
(17) OPNCOD	4.2				OPNCOD
(18) OPNOS	$1		Y = Yes N = No		OPNOS
(19) OPPOS	$1		Y = Yes N = No		OPPOS
(20) OPSOS	$1		Y = Yes N = No		OPSOS
(21) OPNSPOS	$200				OPNSPOS
(22) OPNCOS	4.2				OPNCOS
(24) OPMODNA	1				OPMODNA
(25) OPMOD	$1		1 = Normal 2 = Abnormal		OPMOD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
26	OPSPEC2	$200				OPSPEC2
27	OPMOS	$1		1 = Normal 2 = Abnormal		OPMOS
28	OPSPE2OS	$200				OPSPE2OS
30	OPRODNA	1				OPRODNA
31	OPROD	$1		1 = Normal 2 = Abnormal		OPROD
32	OPSPEC3	$200				OPSPEC3
33	OPROS	$1		1 = Normal 2 = Abnormal		OPROS
34	OPSPE3OS	$200				OPSPE3OS
36	OPPRODNA	1				OPPRODNA
37	OPPROD	$1		1 = Normal 2 = Abnormal		OPPROD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
38	OPSPEC4	$200				OPSPEC4
39	OPPROS	$1		1 = Normal 2 = Abnormal		OPPROS
40	OPSPE4OS	$200				OPSPE4OS

Date of Assessment
(DD/MMM/YYYY)
Derived from Ocular Exam ①

_____

Time of Assessment (24 HR) (Derived from Ocular
Exam) (DD/MMM/YYYY)
Derived from Ocular Exam ②

_____

Eye   Right Eye (OD) ○ ③
                                        Left Eye (OS) ○

Spontaneous orbital pain (CAS)   ④
(Derived from Ocular Exam)

_____

Gaze evoked   ⑤
orbital pain (Derived from Ocular Exam)

_____

Eyelid swelling   ⑥
that is
considered to
be due to active
(inflammatory
phase)
TED (CAS) (Derived from Ocular Exam)

_____

Eyelid Erythema   ⑦
(CAS) (Derived from Ocular Exam)

_____

Conjunctival redness that is considered to be due to active (inflammatory phase) TED (CAS)(Derived from Slit Lamp Examination) ⑧

_____

Chemosis (CAS) (Derived from Slit Lamp Examination) ⑨

_____

Inflammation of caruncle or plica (CAS) (Derived from Slit Lamp Examination) ⑩

_____

Total Score (auto-calculated) _____ ⑪

Investigator Confirmation

Investigator has reviewed the Clinical Activity Score (CAS) ⑬

_____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	OPDAT	dd/MMM/yyyy				OPDAT
2	OPTIM	HH:nn				OPTIM
3	OPEYE	$1		1 = Right Eye (OD) 2 = Left Eye (OS)	1: Right Eye (OD) 2: Left Eye (OS)	OPEYE
4	OPSPON	$10				OPSPON
5	OPGAZE	$10				OPGAZE
6	OPSWEL	$10				OPSWEL
7	OPERY	$10				OPERY
8	OPCONJ	$10				OPCONJ
9	OPCHEM	$10				OPCHEM
10	OPINFLAM	$10				OPINFLAM
11	OPSCORE	$10				OPSCORE
13	OPCON	1				OPCON

Investigator has received and reviewed all Screening laboratory reports and there are no exclusionary results

Yes ◯ **1**
No ◯

Investigator has received and reviewed central ECG report and there are no exclusionary results

Yes ◯ **2**
No ◯

Study Eye (Derived from Eligibility Criteria Screening)

Right Eye (OD) ◯ **3**
Left Eye (OS) ◯

Exophthalmometer reading (Hertel value (mm)) (Derived from Ocular Exam Day 1)

_____ **4**

Was the study eye eligibility reconfirmed before randomization?

Yes ◯ **5**
No ◯

Which study drug presentation will the participant receive throughout the entirety of their participation? (Sent to RTSM)

Lyophilized powder ◯ **6**
Solution ◯

Randomization stratum (Sent to RTSM)

Proptosis >= 23 mm ◯ **7**
Proptosis < 23 mm ◯

RTSM Treatment Period (Sent to RTSM) [Derived]

Period A ⬤ **8**
Period B ◯

Do you wish to randomize participant and dispense study treatment? (Sent to RTSM)

Yes ◯ **9**
No ◯

Randomization Date and Time (Received from RTSM) _____ ⑩

Randomization Date and Time (Local time derived) _____ ⑪

Randomization Number (Received from RTSM) [Hidden] _____ ⑫

Kit Number (Received from RTSM) [Hidden] _____ ⑬

Note: Baseline proptosis on this page is for study eye only.

CTMS Randomization Date [Hidden] _____ ⑮

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	RNINVYN	$1		Y = Yes N = No		RNINVYN
2	RNINVYN2	$1		Y = Yes N = No		RNINVYN2
3	RNEYE	$1		1 = Right Eye (OD) 2 = Left Eye (OS)		RNEYE
4	RNEXO	4.2				RNEXO
5	RNELIG	$1		Y = Yes N = No		RNELIG
6	DISP_Drug Type	1		1 = Lyophilized powder 2 = Solution		DISP_RNSD PRES
7	Proptosis	$1		1 = Proptosis >= 23 mm 2 = Proptosis < 23 mm		RNSTRAT
8	Period	$1		1 = Period A		RNPERIOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Period B		
⑨ RNRAND	$1		Y = Yes N = No		RNRAND
⑩ RANDOMIZ ED_AT	dd/MMM/yy yy HH:nn:ss				RANDOMIZ ED_AT
⑪ RANDDTC	dd/MMM/yy yy HH:nn:ss				RANDDTC
⑫ RAND_ID	12				RAND_ID
⑬ ITEMS	$30				ITEMS
⑮ CTMSRAND	dd/MMM/yy yy				CTMSRAND

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: GRAVES OPHTHALMOPATHY QUALITY OF LIFE SCALE (GO-QOL)
Generated On: 30 May 2025 22:31:51 (GMT)

Was assessment completed?

Yes ◯ ①
No ◯

Date performed (DD/MMM/YYYY)

_____ ②

The following questions deal specifically with your thyroid eye disease. Please focus on the past week while answering
these questions.

During the past week, to what extent were you limited in carrying out the following activities, because of your thyroid eye
disease?

Tick the box that matches your answer. Please tick only one box for each question.

1) Bicycling

Never learned to ride a ◯ ④
bike
Yes, seriously limited ◯
Yes, a little limited ◯
No, not at all limited ◯

2) Driving

No driver's license ◯ ⑤
Yes, seriously limited ◯
Yes, a little limited ◯

No, not at all limited ⭕

3) Moving around the house

Yes, seriously limited ⭕ ⑥
Yes, a little limited ⭕
No, not at all limited ⭕

4) Walking outdoors

Yes, seriously limited ⭕ ⑦
Yes, a little limited ⭕
No, not at all limited ⭕

5) Reading

Yes, seriously limited ⭕ ⑧
Yes, a little limited ⭕
No, not at all limited ⭕

6) Watching TV

Yes, seriously limited ⭕ ⑨
Yes, a little limited ⭕
No, not at all limited ⭕

7) Hobby or pastime

Yes, seriously limited ⭕ ⑩
Yes, a little limited ⭕
No, not at all limited ⭕

8) During the past week, did you feel hindered from something that you wanted to do because of your thyroid
eye disease?

Yes, seriously hindered ⭕ ⑪
Yes, a little hindered ⭕
No, not at all hindered ⭕

Physical Activity Score
(auto-calculate)   (17)

The following questions deal with your thyroid eye disease in general.

9) Do you feel that your appearance has changed because
of your thyroid eye disease?

Yes, very much so ◯ (14)
Yes, a little ◯
No, not at all ◯

10) Do you feel that you are stared at in the streets because of thyroid eye disease?

Yes, very much so ◯ (15)
Yes, a little ◯
No, not at all ◯

11) Do you feel that people react unpleasantly because of
your thyroid eye disease?

Yes, very much so ◯ (16)
Yes, a little ◯
No, not at all ◯

12) Do you feel that your thyroid eye disease has an influence
on your self-confidence?

Yes, very much so ◯ (17)
Yes, a little ◯
No, not at all ◯

13) Do you feel socially isolated because of your thyroid eye disease?

Yes, very much so ◯ (18)
Yes, a little ◯
No, not at all ◯

14) Do you feel that your thyroid eye disease has an influence
on making friends?

Yes, very much so ◯ (19)
Yes, a little ◯

No, not at all ◯

15) Do you feel that you appear less often on photos than
before you had thyroid eye disease?

Yes, very much so ◯ (20)
Yes, a little ◯
No, not at all ◯

16) Do you try to mask changes in appearance caused by
your thyroid eye disease?

Yes, very much so ◯ (21)
Yes, a little ◯
No, not at all ◯

Psychosocial Score
(auto-calculate)

(22)

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	GOQYN	$1		Y = Yes N = No		GOQYN
2	GOQDT	dd/MMM/yy yy				GOQDT
4	GOQBIC	$1		0 = Never learned to ride a bike 1 = Yes, seriously limited 2 = Yes, a little limited 3 = No, not at all limited		GOQBIC
5	GOQDRV	$1		0 = No driver's license 1 = Yes, seriously limited 2 = Yes, a little limited 3 = No, not at all limited		GOQDRV
6	GOQMOVE	$1		1 = Yes, seriously limited		GOQMOVE

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Yes, a little limited 3 = No, not at all limited		
⑦ GOQWALK	$1		1 = Yes, seriously limited 2 = Yes, a little limited 3 = No, not at all limited		GOQWALK
⑧ GOQREAD	$1		1 = Yes, seriously limited 2 = Yes, a little limited 3 = No, not at all limited		GOQREAD
⑨ GOQTV	$1		1 = Yes, seriously limited 2 = Yes, a little limited 3 = No, not at all limited		GOQTV

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑩ GOQHOBBY	$1		1 = Yes, seriously limited 2 = Yes, a little limited 3 = No, not at all limited		GOQHOBBY
⑪ GOQHIND	$1		1 = Yes, seriously hindered 2 = Yes, a little hindered 3 = No, not at all hindered		GOQHIND
⑫ GOQPASCR	5.2				GOQPASCR
⑭ GOQAPP	$1		1 = Yes, very much so 2 = Yes, a little 3 = No, not at all		GOQAPP
⑮ GOQSTRE	$1		1 = Yes, very much so		GOQSTRE

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Yes, a little 3 = No, not at all		
16 GOQREACT	$1		1 = Yes, very much so 2 = Yes, a little 3 = No, not at all		GOQREACT
17 GOQINFLU	$1		1 = Yes, very much so 2 = Yes, a little 3 = No, not at all		GOQINFLU
18 GOQSOCIS	$1		1 = Yes, very much so 2 = Yes, a little 3 = No, not at all		GOQSOCIS
19 GOQINFLU1	$1		1 = Yes, very much so		GOQINFLU1

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Yes, a little 3 = No, not at all		
20 GOQPHOTO	$1		1 = Yes, very much so 2 = Yes, a little 3 = No, not at all		GOQPHOTO
21 GOQMASK	$1		1 = Yes, very much so 2 = Yes, a little 3 = No, not at all		GOQMASK
22 GQOPSSCR	5.2				GQOPSSCR

Did the participant experience any adverse events during the study?　　Yes ◯ **1**
　　No ◯

If Yes, please complete below details.

Is this an ocular event　　Yes ◯ **3**
　　No ◯

If Ocular, select affected eye　　Right Eye (OD) ◯ **4**
　　Left Eye (OS) ◯
　　Both Eyes (OU) ◯

Adverse Event ＿＿＿＿＿＿＿＿＿ **5**

Start Date (DD/MMM/YYYY) ＿＿＿＿＿＿＿＿＿ **6**

Stop Date (DD/MMM/YYYY) ＿＿＿＿＿＿＿＿＿ **7**

Ongoing?　　Yes ◯ **8**
　　No ◯

Is this Adverse Event of Special interest?　　Yes ◯ **9**
　　No ◯

If yes, select event　　Significant infection ◯ **10**
　　Transaminase (ALT or AST) elevations >3 × ULN ◯
　　ANC <1000/mm3 ◯

Platelet count $\bigcirc$
<50,000/mm3
Thromboembolic events $\bigcirc$

Is this event an injection site reaction (ISR)?   Yes $\bigcirc$ **11**

No $\bigcirc$

Select which manifestations are present: (Check all that   **12**
apply)

Pain   _____

Redness   _____ **13**

Swelling   _____ **14**

Ulceration   _____ **15**

Itching   _____ **16**

Induration   _____ **17**

Other   _____ **18**

Other, specify   _____ **19**

Action taken with study treatment   Dose Not Changed $\bigcirc$ **20**

Drug Permanently $\bigcirc$
Discontinued (Withdrawn)

Drug Temporarily $\bigcirc$
Discontinued

Not Applicable ◯
Other ◯

If Other, specify _____ ㉑

Intensity
Grade 1 ◯ ㉒
Grade 2 ◯
Grade 3 ◯
Grade 4 ◯
Grade 5 ◯

Was there a change in Intensity
Yes ◯ ㉓
No ◯

If Yes, Date of Change 1 (DD/MMM/YYYY) _____ ㉔

If Yes, Intensity for the associated AE 1
Grade 1 ◯ ㉕
Grade 2 ◯
Grade 3 ◯
Grade 4 ◯
Grade 5 ◯

If Yes, Action Taken with Study Treatment 1
Dose Not Changed ◯ ㉖
Drug Permanently ◯
Discontinued (Withdrawn)
Drug Temporarily ◯
Discontinued
Not Applicable ◯
Other ◯

If Other, specify _____ 27

If Yes, Date of Change 2 (DD/MMM/YYYY) _____ 28

If Yes, Intensity for the associated AE 2
Grade 1 ◯ 29
Grade 2 ◯
Grade 3 ◯
Grade 4 ◯
Grade 5 ◯

If Yes, Action Taken with Study Treatment 2
Dose Not Changed ◯ 30
Drug Permanently ◯
Discontinued (Withdrawn)
Drug Temporarily ◯
Discontinued
Not Applicable ◯
Other ◯

If Other, specify _____ 31

If Yes, Date of Change 3 (DD/MMM/YYYY) _____ 32

If Yes, Intensity for the associated AE 3
Grade 1 ◯ 33
Grade 2 ◯
Grade 3 ◯
Grade 4 ◯
Grade 5 ◯

If Yes, Action Taken with Study Treatment 3
Dose Not Changed ◯ 34

	Drug Permanently Discontinued (Withdrawn) ◯
	Drug Temporarily Discontinued ◯
	Not Applicable ◯
	Other ◯

If Other, specify _____ **35**

If Yes, Date of Change 4 (DD/MMM/YYYY) _____ **36**

If Yes, Intensity for the associated AE 4

Grade 1 ◯ **37**
Grade 2 ◯
Grade 3 ◯
Grade 4 ◯
Grade 5 ◯

If Yes, Action Taken with Study Treatment 4

Dose Not Changed ◯ **38**
Drug Permanently Discontinued (Withdrawn) ◯
Drug Temporarily Discontinued ◯
Not Applicable ◯
Other ◯

If Other, specify _____ **39**

If Yes, Date of Change 5 (DD/MMM/YYYY) _____ **40**

If Yes, Intensity for the associated AE 5

Grade 1 ◯ **41**
Grade 2 ◯

Grade 3 ◯
Grade 4 ◯
Grade 5 ◯

If Yes, Action Taken with Study Treatment 5

Dose Not Changed ◯ **42**
Drug Permanently ◯
Discontinued (Withdrawn)
Drug Temporarily ◯
Discontinued
Not Applicable ◯
Other ◯

If Other, specify _____ **43**

Causality (Relationship to study drug)

Related ◯ **44**
Unrelated ◯

Treatment of Event **45**

None _____

Concomitant Medication **46**

If Concomitant Medication has been selected, please
record details on Prior and Concomitant Medication page. _____

Concomitant Procedures (47)

If Concomitant Procedures has been selected, please record details on Concomitant Procedures. _____

Is the AE related to a study procedure? Yes ◯ (48)
No ◯

If Yes, specify _____ (49)

Outcome Recovered/Resolved ◯ (50)
Recovered/Resolved With ◯
Sequelae
Not Recovered/Not ◯
Resolved
Recovering/Resolving ◯
Unknown ◯
Fatal ◯
Not Reported ◯

Is this a serious adverse event? Yes ◯ (51)
No ◯

If Serious, check all that apply, complete SAE report form and submit it immediately.

Results in death _____ (52)

If Death, Date of death (DD/MMM/YYYY) _____ **53**

Autopsy Performed

Yes ⬭ **54**
No ⬭
Unknown ⬭

Is life threatening _____ **55**

Requires Inpatient hospitalization or prolongation of existing hospitalization _____ **56**

Results in persistent or significant disability/incapacity _____ **57**

Is a congenital anomaly/birth defect _____ **58**

Important Medical Events _____ **59**

HiddenFieldForCFs _____ **60**

Unique_SAE_No _____ **61**

Unique_AESI_No _____ **62**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	AEYN	$1		Y = Yes N = No		AEYN
3	AEOCULAR	$1		Y = Yes N = No		AEOCULAR
4	AEOCUEYE	$2		1 = Right Eye (OD) 2 = Left Eye (OS) 3 = Both Eyes (OU)		AEOCUEYE
5	AETERM	$200				AETERM
6	AESTDT	dd/MMM/yyyy				AESTDT
7	AEENDAT	dd/MMM/yyyy				AEENDAT
8	AEONGO	$1		Y = Yes N = No		AEONGO
9	AESI	$1		Y = Yes N = No		AESI

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10 AESIEVNT	$1		1 = Significant infection 2 = Transaminase (ALT or AST) elevations >3 × ULN 3 = ANC <1000/mm3 4 = Platelet count <50,000/mm3 5 = Thromboembolic events		AESIEVNT
11 AEISR	$1		Y = Yes N = No		AEISR
12 AEISRP	1				AEISRP
13 AEISRR	1				AEISRR
14 AEISRS	1				AEISRS
15 AEISRU	1				AEISRU
16 AEISRI	1				AEISRI

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17 AEISRIN	1				AEISRIN
18 AEISRO	1				AEISRO
19 AEISRSP	$200				AEISRSP
20 AEACN	$1		1 = Dose Not Changed 2 = Drug Permanently Discontinued (Withdrawn) 3 = Drug Temporarily Discontinued 4 = Not Applicable 5 = Other		AEACN
21 AEACNOTH	$200				AEACNOTH
22 AECTCAE	$1		1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5		AECTCAE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
23	AEGRADEYN	$1		Y = Yes N = No		AEGRADEYN
24	AECTCDT	dd/MMM/yyyy				AECTCDT
25	AECTCAE1	$1		1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5		AECTCAE1
26	AEACN1	$1		1 = Dose Not Changed 2 = Drug Permanently Discontinued (Withdrawn) 3 = Drug Temporarily Discontinued 4 = Not Applicable 5 = Other		AEACN1
27	AEACNOT1	$200				AEACNOT1

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
28	AECTCDT1	dd/MMM/yyyy				AECTCDT1
29	AECTCAE2	$1		1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5		AECTCAE2
30	AEACN2	$1		1 = Dose Not Changed 2 = Drug Permanently Discontinued (Withdrawn) 3 = Drug Temporarily Discontinued 4 = Not Applicable 5 = Other		AEACN2
31	AEACNOT2	$200				AEACNOT2
32	AECTCDT2	dd/MMM/yyyy				AECTCDT2
33	AECTCAE3	$1		1 = Grade 1		AECTCAE3

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5		
34 AEACN3	$1		1 = Dose Not Changed 2 = Drug Permanently Discontinued (Withdrawn) 3 = Drug Temporarily Discontinued 4 = Not Applicable 5 = Other		AEACN3
35 AEACNOT3	$200				AEACNOT3
36 AECTCDT3	dd/MMM/yyyy				AECTCDT3
37 AECTCAE4	$1		1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5		AECTCAE4

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
38 AEACN4	$1		1 = Dose Not Changed 2 = Drug Permanently Discontinued (Withdrawn) 3 = Drug Temporarily Discontinued 4 = Not Applicable 5 = Other		AEACN4
39 AEACNOT4	$200				AEACNOT4
40 AECTCDT4	dd/MMM/yyyy				AECTCDT4
41 AECTCAE5	$1		1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5		AECTCAE5

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(42) AEACN5	$1		1 = Dose Not Changed 2 = Drug Permanently Discontinued (Withdrawn) 3 = Drug Temporarily Discontinued 4 = Not Applicable 5 = Other		AEACN5
(43) AEACNOT5	$200				AEACNOT5
(44) AEREL	$1		1 = Related 2 = Unrelated		AEREL
(45) AETRTNON	1				AETRTNON
(46) AETRTCM	1				AETRTCM
(47) AETRTCP	1				AETRTCP
(48) AEREL1	$1		Y = Yes N = No		AEREL1

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
49	AESPEC	$200				AESPEC
50	AEOUT	$1		1 = Recovered/ Resolved 2 = Recovered/ Resolved With Sequelae 3 = Not Recovered/ Not Resolved 4 = Recovering/ Resolving 5 = Unknown 6 = Fatal 7 = Not Reported		AEOUT
51	AESER	$1		Y = Yes N = No		AESER
52	AESDTH	1				AESDTH
53	AESDTHDT	dd/MMM/yy yy				AESDTHDT
54	AEAUTYN	$2		Y = Yes N = No		AEAUTYN

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			UN = Unknown		
55 AESLIFE	1				AESLIFE
56 AESHOSP	1				AESHOSP
57 AEDISAB	1				AEDISAB
58 AESCONG	1				AESCONG
59 AESMIE	1				AESMIE
60 H_NOW	dd MMM yyyy HH:nn:ss				H_NOW
61 CASEID	$100				CASEID
62 AESI_ID	$100				AESI_ID

The Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) report form must be completed and submitted to sponsor within 24 hours of receiving information about the event.

Type of Report

| Type of Report | Initial ◯ ③ |
| | Follow Up ◯ |

If follow up, Date of Report _____ ④

Event Type

SAE _____ ⑥

AESI _____ ⑦

Date and Time Investigator became aware of SAE/AESI (DD/MMM/YYYY) _____ ⑧

Reporter Information

Principal Investigator Name _____ ⑩

Country
[Derived] ⑪
_____

Country of event occurrence, if different from Site country ⑫

Participant Information

Age at Time of Event Onset (Years) ⑭

Sex
[Derived]

Male ⃝ ⑮
Female ⃝

Weight at Time of Event Onset

kg ⃝ ⑯
lb ⃝

Height (cm)
[Derived] ⑰

Race

White
[Derived] ⑲

Black or African American
[Derived] ⑳

Asian
[Derived] ㉑

American Indian or Alaska Native
[Derived]   (27)

Native Hawaiian or Other Pacific Islander
[Derived]   (23)

Unknown
[Derived]   (24)

Other
[Derived]   (25)

If Other, please specify
[Derived]   (26)

Ethnicity   Hispanic or Latino ◯ (27)
[Derived]   Not Hispanic or Latino ◯
                                                              Not Reported ◯
                                                                   Unknown ◯

Event Information

Adverse Event
[Derived]   (29)

Adverse Event (Additional Details of AE e.g. 'worsening') _____ (30)

Onset Date (DD/MMM/YYYY) _____ **31**

Onset Time (24 HR) _____ **32**

Resolution Date (DD/MMM/YYYY) _____ **33**

Resolution Time (24HR) _____ **34**

Outcome
[Derived]

Recovered/Resolved ◯ **35**
Recovered/Resolved With ◯
Sequelae
Not Recovered/Not ◯
Resolved
Recovering/Resolving ◯
Unknown ◯
Fatal ◯
Not Reported ◯

Intensity

Grade 1 ◯ **36**
Grade 2 ◯
Grade 3 ◯
Grade 4 ◯
Grade 5 ◯

Causality (Relationship to study drug)
[Derived]

Related ◯ **37**
Unrelated ◯

If not considered related to IP, provide alternate causality: _____ **38**

Relationship to study procedure?   Yes◯ **39**
                                     No◯

Serious Criteria (check all that apply)

Death (to be reported only if participant has died due to the reported AE) _____ **41**

 Date of death (DD/MMM/YYYY)
 [Derived]   _____ **42**

Autopsy Performed
[Derived]   Yes◯ **43**
                                     No◯
                                Unknown◯

Cause of Death   _____ **44**

Life-threatening   _____ **45**

Inpatient hospitalization or prolongation of existing hospitalization   _____ **46**

 Hospital Admission Date (DD/MMM/YYYY)   _____ **47**

 Discharge Date (DD/MMM/YYYY)   _____ **48**

Persistent or significant disability/incapacity   _____ **49**

Congenital anomaly or birth defect _____ (50)

Important Medical Event _____ (51)

AESI Event Type (check all that apply)

Transaminase (ALT or AST) elevations >3 × ULN _____ (53)

Absolute Neutrophil Count (ANC) less than 1000/mm3 _____ (54)

Platelet count less than 50,000/mm3 _____ (55)

Thromboembolic events (includes thrombotic events as well as thromboembolism) _____ (56)

Significant Infection (57)

If Significant Infection is checked, then additionally select all criteria that apply. _____

  Infection that meets any SAE criteria _____ (58)

  Confirmed opportunistic infection, with the exception of localized thrush or other localized yeast infection without complications (59) _____

  Infection requiring prolonged medications (>14 days) _____ (60)

  Infection requiring any parenteral treatment _____ (61)

Investigational Product Information

Study drug not started (in screening) _____ 63

Investigational Product   TOUR006 64

Frequency   every 8 weeks 65

Route   Subcutaneous Injection 66

Start Date (DD/MMM/YYYY) (Derived from Visit 1/Day 1   67
Study Drug Administration – Date of Study Drug
Administration) _____

Date of Last Dose of Study Drug Prior to Event Onset   68
(DD/MMM/YYYY) _____

Was Study Drug Unmasked?   Yes ◯ 69
                                                      No ◯

If Yes, Name of Person Who Performed Unmasking _____ 70

Was Sponsor Notified Prior to Unmasking?   Yes ◯ 71
                                                      No ◯

Action taken with study treatment   Dose Not Changed ◯ 72
                                               Drug Permanently ◯
                                          Discontinued (Withdrawn)

Drug Temporarily Discontinued ◯
Not Applicable ◯
Other/Unknown ◯

If Other/Unknown, specify _____ (73)

If Drug Permanently or Temporarily Discontinued, please complete the following section

Discontinuation Date (DD/MMM/YYYY) _____ (75)

Did the Event Stop After Study Drug Discontinuation? Yes ◯ (76)
No ◯

If Dose Changed, please complete the following section

Date of Change (DD/MMM/YYYY) _____ (78)

Dose/Unit _____ (79)

Route _____ (80)

Frequency _____ (81)

Event Description

Provide a detailed chronological summary of the event
from onset to resolution,
including any treatments provided, procedures
performed and laboratory/diagnostic
testing relevant to the reported event.

(83)

Continuation of Event Description

(84)

Continuation of Event Description

(85)

Continuation of Event Description

(86)

Continuation of Event Description

(87)

Investigator Confirmation

Investigator Name
[Derived]

(89)

Investigator Confirmation Date and Time
[Derived]

(90)

AE Number (Record Position from AE form)
[Hidden]

(91)

Unique_AESI_No

(92)

HiddenFieldForCFs _____ 93

HIDDEN field for edits _____ 94

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③	AESIRPTP	$1		1 = Initial 2 = Follow Up		AESIRPTP
④	AESIDRDT	dd/MMM/yyyy				AESIDRDT
⑥	AESAE	1				AESAE
⑦	AEAESI	1				AESI
⑧	AESIINDT	dd/MMM/yyyy HH:nn				AESIINDT
⑩	AESIPI	$40				AESIPI
⑪	AESICNTR	$3				AESICNTR
⑫	AESICNTR1	$3				AESICNTR1
⑭	AESIAGE	3				AESIAGE
⑮	AESISEX	$1		M = Male F = Female		AESISEX
⑯	AESIWGT	5.2	kg = kg lb = lb			AESIWGT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(17)	AESIHGT	5.2				AESIHGT
(19)	AESIRAC5	1				AESIRAC5
(20)	AESIRAC3	1				AESIRAC3
(21)	AESIRAC2	1				AESIRAC2
(22)	AESIRAC1	1				AESIRAC1
(23)	AESIRAC4	1				AESIRAC4
(24)	AESIRAC7	1				AESIRAC7
(25)	AESIRAC8	1				AESIRAC8
(26)	RACEOTH	$200				RACEOTH
(27)	AESIETH	$2		1 = Hispanic or Latino 2 = Not Hispanic or Latino 3 = Not Reported 4 = Unknown		AESIETH

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(29) AESITERM	$200				AESITERM
(30) AESITERM1	$200				AESITERM1
(31) AESISTDT	dd/MMM/yyyy				AESISTDT
(32) AESITIM	HH:nn				AESITIM
(33) AESIRSDT	dd/MMM/yyyy				AESIRSDT
(34) AESIRSTM	HH:nn				AESIRSTM
(35) AESIOUT	$2		1 = Recovered/ Resolved 2 = Recovered/ Resolved With Sequelae 3 = Not Recovered/ Not Resolved 4 = Recovering/ Resolving		AESIOUT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				5 = Unknown 6 = Fatal 7 = Not Reported		
36	AESIGRAD	$1		1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5		AESIGRAD
37	AESIREL	$1		1 = Related 2 = Unrelated		AESIREL
38	AESICAS	$200				AESICAS
39	AESIRELYN	$2		Y = Yes N = No		AESIREL1
41	AESIDTH	1				AESIDTH
42	AESIDTDT	dd/MMM/yyyy				AESIDTDT
43	AESIAUTO	$2		Y = Yes N = No UN = Unknown		AESIAUTO

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
44	AESICAUSE	$200				AESICAUSE
45	AESILIFE	1				AESILIFE
46	AESIHOSP	1				AESIHOSP
47	AESIHSDT	dd/MMM/yyyy				AESIHSDT
48	AESIDDT	dd/MMM/yyyy				AESIDDT
49	AESIDIS	1				AESIDIS
50	AESICONG	1				AESICONG
51	AESIMED	1				AESIMED
53	AESILIV	1				AESILIV
54	AESINEUT	1				AESINEUT
55	AESITCP	1				AESITCP
56	AESITEE	1				AESITEE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
57	AESISINF	1				AESISINF
58	SGINF1	1				SGINF1
59	SGINF2	1				SGINF2
60	SGINF3	1				SGINF3
61	SGINF4	1				SGINF4
63	AESIDNS	1				AESIDNS
64	AESIPI1	$15		TOUR006		AESIPI1
65	AESIFREQ	$20		every 8 weeks		AESIFREQ
66	AESIROUT	$25		Subcutaneous Injection		AESIROUT
67	AESIDADT	dd/MMM/yyyy				AESIDADT
68	AESIDLDT	dd/MMM/yyyy				AESIDLDT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
69	AESIUNYN	$1		Y = Yes N = No		AESIUNYN
70	AESIUNME	$40				AESIUNME
71	AESINOTF	$1		Y = Yes N = No		AESINOTF
72	AESIACN	$1		1 = Dose Not Changed 2 = Drug Permanently Discontinued (Withdrawn) 3 = Drug Temporarily Discontinued 4 = Not Applicable 5 = Other/Unknown		AESIACN
73	AEACNOTH	$200				AEACNOTH
75	AESIWDT	dd/MMM/yyyy				AESIWDT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
76	AESIRST	$1		Y = Yes N = No		AESIRST
78	AESIDSDT	dd/MMM/yy yy				AESIDSDT
79	AESIDOSE	$20				AESIDOSE
80	SAEROUT1	$20				SAEROUT1
81	SAEFREQ1	$20				SAEFREQ1
83	AESIDES	$200				AESIDES
84	AESIDES1	$200				AESIDES1
85	AESIDES2	$200				AESIDES2
86	AESIDES3	$200				AESIDES3
87	AESIDES5	$200				AESIDES5
89	AESIIVNM	$40				AESIIVNM
90	AESIIVDT	dd/MMM/yy yy HH:nn				AESIIVDT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(91)	AESINUM	4				AESINUM
(92)	AESI_ID	$100				AESI_ID
(93)	H_NOW	dd MMM yyyy HH:nn:ss				H_NOW
(94)	AESISDER	dd/MMM/yy yy HH:nn				AESISDER

Medical/ Surgical /Allergy History

Yes ◯ **①**
No ◯

Is the event related to any Medical/Surgical/Allergy History?

Relevant Medical History 1 **②**

[Dynamic Search List] _____

Relevant Medical History 2 **③**

[Dynamic Search List]

_____

Relevant Medical History 3 **④**

[Dynamic Search List] _____

Relevant Medical History 4 **⑤**

[Dynamic Search List] _____

Relevant Medical History 5 **⑥**

[Dynamic Search List] _____

Concomitant Medications   Yes ◯ ⑦
                                                                    No ◯

Were there any relevant Concomitant Medications?

Relevant Concomitant Medication 1   ⑧
[Dynamic Search List]

_____

Relevant Concomitant Medication 2   ⑨
[Dynamic Search List]   _____

Relevant Concomitant Medication 3   ⑩
[Dynamic Search List]   _____

Relevant Concomitant Medication 4   ⑪
[Dynamic Search List]   _____

Relevant Concomitant Medication 5   ⑫
[Dynamic Search List]   _____

Concomitant Procedures and Surgeries Relevant to   Yes ◯ ⑬
SAE/AESI   No ◯

Were there any Concomitant Procedures and Surgeries
relevant
to this SAE/AESI?

Relevant Concomitant Procedure 1
[Dynamic Search List]   (14)

_____

Relevant Concomitant Procedure 2
[Dynamic Search List]   (15)

_____

Relevant Concomitant Procedure 3
[Dynamic Search List]   (16)

_____

Relevant Concomitant Procedure 4
[Dynamic Search List]   (17)

_____

Relevant Concomitant Procedure 5
[Dynamic Search List]   (18)

_____

Relevant laboratory or diagnostic test results   Yes ◯ (19)
                                                                              No ◯

Were any laboratory or diagnostic tests performed
related to this
event?

_____

Laboratory or Diagnostic Test

Laboratory Test ◯ **20**
Diagnostic Test ◯

For Laboratory Tests complete Test Name, Test Date, Test Result, Test Units, Normal Low Range, Normal High Range

For Diagnostic Test complete Test Name, Test Date and Diagnostic Test Results

Test Name _____ **21**

Test Date _____ **22**

Test Result _____ **23**

Test Units _____ **24**

Normal Low Range _____ **25**

Normal High Range _____ **26**

Diagnostic Test Result _____ **27**

Investigator Confirmation

I confirm I have reviewed this SAE/AESI report _____ (29)

Investigator Name (30)
[Derived]

_____

Investigator Confirmation Date and Time (31)
[Derived]

_____

Please note, selecting this field provides confirmation that the data on the Serious Adverse Event (SAE)/Adverse Event of Special Interest (AESI) Report forms is accurate. Please make every effort to enter all available relevant data on both SAE/AESI Report forms before submitting the forms.

Submit SAE/AESI to Pharmacovigilance _____ (33)

Date of SAE/AESI Submission and Time (34)
[Derived]

_____

Only complete the following two questions if the SAE/AESI has been completed in error and should be inactivated from the Safety database.

If this Serious Adverse Event /Adverse Event of Special
Interest should be Nullified (e.g.
because it was reported by an error) please check box _____ **36**

Reason for Nullification _____ **37**

Unique_AESI_No _____ **38**

HiddenFieldForCFs _____ **39**

HiddenFieldForCFs - Log _____ **40**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	MHYN	$1		Y = Yes N = No		MHYN
2	CMDSL1	$200				CMDSL1
3	CMDSL2	$200				CMDSL2
4	CMDSL3	$200				CMDSL3
5	CMDSL4	$200				CMDSL4
6	CMDSL5	$200				CMDSL5
7	CMYN	$1		Y = Yes N = No		CMYN
8	RCMDSL	$200				RCMDSL
9	RCMDSL1	$200				RCMDSL1
10	RCMDSL2	$200				RCMDSL2
11	RCMDSL3	$200				RCMDSL3
12	RCMDSL4	$200				RCMDSL4

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
13	CPYN	$1		Y = Yes N = No		CPYN
14	RCPDSL	$200				RCPDSL
15	RCPDSL1	$200				RCPDSL1
16	RCPDSL2	$200				RCPDSL2
17	RCPDSL3	$200				RCPDSL3
18	RCPDSL4	$200				RCPDSL4
19	LBYN	$1		Y = Yes N = No		LBYN
20	LBTEST	$1		1 = Laboratory Test 2 = Diagnostic Test		LBTEST
21	LBNAME	$200				LBNAME
22	LBDATE	dd/MMM/yyyy				LBDATE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
23	LBRES	$40				LBRES
24	LBUNIT	$40				LBUNIT
25	LBNLR	$40				LBNLR
26	LBNHR	$40				LBNHR
27	LBDTRES	$40				LBDTRES
29	AESICONF	1				AESICONF
30	AESIIVNM	$40				AESIIVNM
31	AESIINDT	dd/MMM/yyyy HH:nn				AESIINDT
33	AESISBMT	1				AESISBMT
34	AESIDT	dd/MMM/yyyy HH:nn				AESIDT
36	AESINULL	1				AESINULL
37	AESIREAS	$200				AESIREAS

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
38	AESI_ID	$100				AESI_ID
39	H_NOW	dd MMM yyyy HH:nn:ss				H_NOW
40	H_NOW_LOG	dd MMM yyyy HH:nn:ss				H_NOW_LOG

Did the participant receive any prior and/or concomitant medications?

Yes ◯ **1**
No ◯

Drug name _____ **2**

Is this an ocular medication?

Yes ◯ **3**
No ◯

If Ocular, select treated eye

Right Eye (OD) ◯ **4**
Left Eye (OS) ◯
Both Eyes (OU) ◯

Indication:

If Rescue Therapy, then please also fill out the TED Rescue Therapy and Intervention form.

Adverse Event ◯ **5**
Medical/Ocular History ◯
Underlying Disease ◯
(Graves' Disease / Thyroid
Eye Disease [TED])
Prophylaxis ◯
Rescue Medication ◯
Concomitant Procedure ◯
Other ◯

If Prophylaxis or Other, please specify _____ **6**

If Adverse Event, please select AE 1 [Dynamic Search List] _____ **7**

If Adverse Event, please select AE 2 [Dynamic Search List] _____ **8**

If Adverse Event, please select AE 3 [Dynamic Search List]   ⑨

_____

If Adverse Event, please select AE 4 [Dynamic Search List]   ⑩

_____

If Adverse Event, please select AE 5 [Dynamic Search List]   ⑪

_____

If Medical History, please select MH 1 [Dynamic Search List]   ⑫

_____

If Medical History, please select MH 2 [Dynamic Search List]   ⑬

_____

If Medical History, please select MH 3 [Dynamic Search List]   ⑭

_____

If Medical History, please select MH 4 [Dynamic Search List]   ⑮

_____

If Medical History, please select MH 5 [Dynamic Search List]   ⑯

_____

If Rescue Medication, please select RM 1 [Dynamic Search List]   ⑰

_____

If Rescue Medication, please select RM 2 [Dynamic Search List]   ⑱

_____

If Rescue Medication, please select RM 3 [Dynamic Search List]   ⑲

_____

If Rescue Medication, please select RM 4 [Dynamic Search List] ⟨20⟩

If Rescue Medication, please select RM 5 [Dynamic Search List] ⟨21⟩

If Concomitant Procedure, please select CP 1 [Dynamic Search List] ⟨22⟩

If Concomitant Procedure, please select CP 2 [Dynamic Search List] ⟨23⟩

If Concomitant Procedure, please select CP 3 [Dynamic Search List] ⟨24⟩

If Concomitant Procedure, please select CP 4 [Dynamic Search List] ⟨25⟩

If Concomitant Procedure, please select CP 5[Dynamic Search List] ⟨26⟩

Start Date (DD/MMM/YYYY)
[Allow partial date i.e. UN/UNK/YYYY] ⟨27⟩

Ongoing? ⟨28⟩

End Date (DD/MMM/YYYY)
[Allow partial date i.e. UN/UNK/YYYY] ⟨29⟩

Dose ⟨30⟩

Unit

- g ㉛
- mg
- ug
- ng
- mg/kg
- mg/m2
- ug/kg
- ug/m2
- mL
- mL/kg
- L
- IU
- kIU
- IU/kg
- %
- mEq
- mmol
- umol
- MBq
- mCi
- TABLET
- CAPSULE
- PUFF
- gtt
- Teaspoon
- Tablespoon
- Unknown
- Other

If Other, please specify _____ ㉜

Route

Oral ◯ **33**
Intravenous ◯
Intramuscular ◯
Subcutaneous ◯
Rectal ◯
Nasal ◯
Intravitreal ◯
Sublingual ◯
Respiration (inhalation) ◯
Transdermal ◯
Buccal ◯
Topical (Skin) ◯
Topical (Ophthalmic) ◯
Vaginal ◯
Other ◯

If Other, please specify _____ **34**

Frequency

QH - each hour ◯ **35**
QD - once a day ◯
BID - Twice a day ◯
TID - 3 times a day ◯
QID - four times a day ◯
QOD - every other day ◯
EVERY WEEK ◯
2 TIMES PER WEEK ◯
3 TIMES PER WEEK ◯
4 TIMES PER WEEK ◯
QM - every morning ◯
PRN - as needed ◯

ONCE ◯
Q2H - every 2 hours ◯
Q4H - every 4 hours ◯
Other ◯

If Other, please specify _____ **36**

Hidden field for CFs _____ **37**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	CMYN	$1		Y = Yes N = No		CMYN
2	CMTRT	$200				CMTRT
3	CMOCYN	$1		Y = Yes N = No		CMOCYN
4	CMEYE	$1		1 = Right Eye (OD) 2 = Left Eye (OS) 3 = Both Eyes (OU)		CMEYE
5	CMINDC	$2		1 = Adverse Event 2 = Medical/Ocular History 6 = Underlying Disease (Graves' Disease / Thyroid Eye Disease [TED])		CMINDC

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Prophylaxis 4 = Rescue Medication 5 = Concomitant Procedure 99 = Other		
⑥ CMINDCO	$200				CMINDCO
⑦ CMAEDSL1	$200				CMAEDSL1
⑧ CMAEDSL2	$200				CMAEDSL2
⑨ CMAEDSL3	$200				CMAEDSL3
⑩ CMAEDSL4	$200				CMAEDSL4
⑪ CMAEDSL5	$200				CMAEDSL5
⑫ CMMHDSL1	$200				CMMHDSL1
⑬ CMMHDSL2	$200				CMMHDSL2
⑭ CMMHDSL3	$200				CMMHDSL3
⑮ CMMHDSL4	$200				CMMHDSL4

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
16	CMMHDSL5	$200				CMMHDSL5
17	CMRMDSL1	$200				CMRMDSL1
18	CMRMDSL2	$200				CMRMDSL2
19	CMRMDSL3	$200				CMRMDSL3
20	CMRMDSL4	$200				CMRMDSL4
21	CMRMDSL5	$200				CMRMDSL5
22	CMCPDSL1	$200				CMCPDSL1
23	CMCPDSL2	$200				CMCPDSL2
24	CMCPDSL3	$200				CMCPDSL3
25	CMCPDSL4	$200				CMCPDSL4
26	CMCPDSL5	$200				CMCPDSL5
27	CMSTDT	dd-/MMM-/yyyy				CMSTDT
28	CMONGO	1				CMONGO

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
29 CMENDAT	dd-/MMM-/yyyy				CMENDAT
30 CMDOSE	12.2				CMDOSE
31 CMDOSU	$2		1 = g 2 = mg 3 = ug 4 = ng 5 = mg/kg 6 = mg/m2 7 = ug/kg 8 = ug/m2 9 = mL 10 = mL/kg 11 = L 12 = IU 13 = kIU 14 = IU/kg 15 = % 16 = mEq 17 = mmol 18 = umol 19 = MBq 20 = mCi 21 = TABLET 22 = CAPSULE 23 = PUFF 24 = gtt 25 = Teaspoon 26 = Tablespoon		CMDOSU

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			92 = Unknown 99 = Other		
(37) CMDOSUO	$200				CMDOSUO
(38) CMROUTE	$2		1 = Oral 2 = Intravenous 3 = Intramuscular 4 = Subcutaneous 5 = Rectal 6 = Nasal 7 = Intravitreal 8 = Sublingual 9 = Respiration (inhalation) 10 = Transdermal 11 = Buccal 12 = Topical (Skin) 13 = Topical (Ophthalmic)		CMROUTE

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = Vaginal 99 = Other		
③④ CMROUTO	$200				CMROUTO
③⑤ CMDOSFRQ	$2		1 = QH - each hour 2 = QD - once a day 3 = BID - Twice a day 4 = TID - 3 times a day 5 = QID - four times a day 6 = QOD - every other day 7 = EVERY WEEK 8 = 2 TIMES PER WEEK 9 = 3 TIMES PER WEEK 10 = 4 TIMES PER WEEK 11 = QM - every morning		CMDOSFRQ

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = PRN - as needed 13 = ONCE 14 = Q2H - every 2 hours 15 = Q4H - every 4 hours 99 = Other		
�36 CMDFRQOT	$200				CMDFRQOT
㊲ H_NOW	dd MMM yyyy HH:nn:ss				H_NOW

Did the participant have any concomitant procedures?　　Yes ◯ **1**
　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Procedure name　　　　　　　　　　　　　　　　　　_____ **2**

Start Date of Procedure (DD/MMM/YYYY)[Allow partial
date i.e. UN/UNK/YYYY]　　　　　　　　　　　　　　_____ **3**

End Date of Procedure (DD/MMM/YYYY)　　　　　　　　　　　　　**4**
[Allow partial date i.e. UN/UNK/YYYY]

　　　　　　　　　　　　　　　　　　　　　　　　　_____

Is this an Ocular procedure?　　　　　　　　　　　　Yes ◯ **5**
　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

　If Yes: Which Eye?　　　　　　　　　　　　Right Eye (OD) ◯ **6**
　　　　　　　　　　　　　　　　　　　　　　Left Eye (OS) ◯
　　　　　　　　　　　　　　　　　　　　　　Both Eyes (OU) ◯

Indication (Check all that apply):　　　　　　　　　　　　　　**7**

Adverse Event　　　　　　　　　　　　　　　　　　_____

Medical/Ocular History　　　　　　　　　　　　　　_____ **8**

Underlying Disease (Graves' Disease / Thyroid Eye　　　　　　　**9**
Disease [TED])　　　　　　　　　　　　　　　　　_____

Rescue Intervention ⑩

If Rescue Therapy, then please also fill out the TED
Rescue Therapy and Intervention form. _____

Other _____ ⑪

 If Other, please specify _____ ⑫

If Adverse Event, please select AE 1 ⑬
[Dynamic search list]

_____

If Adverse Event, please select AE 2 ⑭
[Dynamic search list] _____

If Adverse Event, please select AE 3 ⑮
[Dynamic search list] _____

If Adverse Event, please select AE 4 ⑯
[Dynamic search list] _____

If Adverse Event, please select AE 5 ⑰
[Dynamic search list] _____

If Medical History, please select MH 1 ⑱
[Dynamic search list] _____

If Medical History, please select MH 2
[Dynamic search list]   ⑲

If Medical History, please select MH 3
[Dynamic search list]   ⑳

If Medical History, please select MH 4
[Dynamic search list]   ㉑

If Medical History, please select MH 5
[Dynamic search list]   ㉒

Hidden field for CFs.   ㉓

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	CPYN	$1		Y = Yes N = No		CPYN
2	CPTRT	$200				CPTRT
3	CPSTDT	dd-/MMM-/YYYY				CPSTDT
4	CPENDT	dd-/MMM-/YYYY				CPENDT
5	CPOCLYN	$1		Y = Yes N = No		CPOCLYN
6	CPEYE	$1		1 = Right Eye (OD) 2 = Left Eye (OS) 3 = Both Eyes (OU)		CPEYE
7	CPINDCAE	1				CPINDCAE
8	CPINDCMH	1				CPINDCMH
9	CPINDCDIS	1				CPINDCDIS
10	CPINDRES	1				CPRESC

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	CPINDOTH	1				CPINDOTH
12	CPOTHSPEC	$200				CPOTHSPEC
13	CPAEDSL1	$200				CPAEDSL1
14	CPAEDSL2	$200				CPAEDSL2
15	CPAEDSL3	$200				CPAEDSL3
16	CPAEDSL4	$200				CPAEDSL4
17	CPAEDSL5	$200				CPAEDSL5
18	CPMHDSL1	$200				CPMHDSL1
19	CPMHDSL2	$200				CPMHDSL2
20	CPMHDSL3	$200				CPMHDSL3
21	CPMHDSL4	$200				CPMHDSL4
22	CPMHDSL5	$200				CPMHDSL5

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(25) H_NOW	dd MMM yyyy HH:nn:ss				H_NOW

Was treatment completed per protocol for period A?　　Yes ◯ **①**
No ◯

Date of last dose (DD/MMM/YYYY)　　_____ **②**

If No, please complete below

Primary reason for treatment discontinuation (If Death
then please complete the Death Form.)

Adverse Event ◯ **④**
TED disease progression ◯
that required rescue
therapy
Non Compliance ◯
Withdrawal of consent ◯
Lost to follow up ◯
Death ◯
Pregnancy ◯
Site terminated by Sponsor ◯
Study terminated by ◯
Sponsor
Other ◯

If primary reason is Adverse Event, please select AE
[Dynamic Search List]　　_____ **⑤**

If Non Compliance, please specify　　_____ **⑥**

If Other, please specify　　_____ **⑦**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① DPYN	$2		Y = Yes N = No		DPYN
② DPDAT	dd/MMM/yyyy				DPDAT
④ DPPRIMR	$2		1 = Adverse Event 2 = TED disease progression that required rescue therapy 3 = Non Compliance 4 = Withdrawal of consent 5 = Lost to follow up 6 = Death 7 = Pregnancy 8 = Site terminated by Sponsor 9 = Study terminated by Sponsor 10 = Other		DPPRIMR

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑤ DPDSL	$200				DPDSL
⑥ DPNONC	$200				DPNONC
⑦ DPOTH	$200				DPOTH

Was treatment completed per protocol for period B?   Yes ◯ **①**
                                                        No ◯

Date of last dose (DD/MMM/YYYY)   _____ **②**

If No, please complete below

Primary reason for treatment discontinuation (If Death then please complete the Death Form.)

Adverse Event ◯ **④**
TED disease progression ◯
that required rescue
therapy
Non Compliance ◯
Withdrawal of consent ◯
Lost to follow up ◯
Death ◯
Pregnancy ◯
Site terminated by Sponsor ◯
Study terminated by ◯
Sponsor
Other ◯

If primary reason is Adverse Event, please select AE [Dynamic Search List]   _____ **⑤**

If Non Compliance, please specify   _____ **⑥**

If Other, please specify   _____ **⑦**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① DPYN	$2		Y = Yes N = No		DPYN
② DPDAT	dd/MMM/yy yy				DPDAT
④ DPPRIMR	$2		1 = Adverse Event 2 = TED disease progression that required rescue therapy 3 = Non Compliance 4 = Withdrawal of consent 5 = Lost to follow up 6 = Death 7 = Pregnancy 8 = Site terminated by Sponsor 9 = Study terminated by Sponsor 10 = Other		DPPRIMR

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑤ DPDSL	$200				DPDSL
⑥ DPNONC	$200				DPNONC
⑦ DPOTH	$200				DPOTH

Did the Participant complete the study per Protocol? Yes ◯ **1**
No ◯

Date of completion or early withdrawal (DD/MMM/YYYY) _____ **2**

If the participant did not complete the study per protocol, what was the primary reason for early withdrawal?
(If Death then please complete the Death Form)

Adverse Event ◯ **3**
Non Compliance ◯
Withdrawal of consent ◯
Lost to follow up ◯
Death ◯
Site terminated by Sponsor ◯
Study terminated by Sponsor ◯
Other ◯

If primary reason is Adverse Event, please select AE
[Dynamic Search List] _____ **4**

If Non Compliance, please specify _____ **5**

If Other, please specify _____ **6**

RTSM Deactivate Subject? (Hidden) _____ **7**

RTSM Deactivation Reason (Hidden) _____ **8**

CTMS Completion Date(hidden) _____ **9**

CTMS Early Terminated Date (hidden) _____ **10**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① EOSYN	$1		Y = Yes N = No		EOSYN
② EOSDAT	dd/MMM/yyyy				EOSDAT
③ EOSREASN	$2		1 = Adverse Event 2 = Non Compliance 3 = Withdrawal of consent 4 = Lost to follow up 5 = Death 6 = Site terminated by Sponsor 7 = Study terminated by Sponsor 99 = Other		EOSREASN
④ EOSAEDSL	$200				EOSAEDSL
⑤ EOSSPEC	$200				EOSSPEC
⑥ EOSOTH	$200				EOSOTH

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦	SUBJ_DEAC TIV	1				SUBDEA
⑧	BLNCE_DEA CTIV_REAS ON	$200				BLNCE_DEA CTIV_REAS ON
⑨	CTMSCOMP	dd/MMM/yy yy				CTMSCOMP
⑩	CTMSET	dd/MMM/yy yy				CTMSET

Please also enter relevant information in the Concomitant Medication or Concomitant Procedure form for the rescue therapy or intervention used. Please also enter the relevant information in the Adverse Event form, as the event of significant and acute clinical deterioration in TED should also be reported as an AE.

Did the participant receive any TED Rescue therapy or intervention after the participant signed the informed consent?

Yes ◯ ②
No ◯

If Yes, please specify below TED Rescue therapy or Rescue Intervention.

Date of performed intervention(DD/MMM/YYYY) _____ ③

Time of intervention (24HR) _____ ④

Check if Time of intervention is unknown _____ ⑤

Rescue therapy or intervention

Systemic corticosteroids ◯ ⑥
Teprotumumab ◯
Orbital decompression ◯
Orbital irradiation ◯
Other ◯

If Other, please specify _____ ⑦

Eye with significant and acute clinical deterioration in TED

Right Eye (OD) ◯ ⑧
Left Eye (OS) ◯

Both Eyes (OU) ◯

(9)

Which of the following criteria for significant and acute clinical deterioration in their TED was met? Select at least one.

Sight-threatening complication (e.g., optic nerve compression)

_____

(10)

Significantly and acutely worsening vision that may otherwise become irreversible, such as: decrease in best corrected visual acuity by 2 or more lines on the Snellen chart from baseline, a new visual field defect, or color defect secondary to optic nerve involvement.

_____

(11)

Other eye-threatening deterioration (e.g., afferent pupillary defect, rise in intraocular pressure, development of corneal infiltrates [keratitis] or corneal ulcer) that an investigator determines to warrant the use of rescue therapy/ intervention.

_____

(12)

Please provide any additional information as needed in relation to the
significant and acute clinical deterioration experienced by the trial participant

_____

(13)

Did the reason for rescue therapy/intervention resolve after use?

Yes ◯
No ◯

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② TEDYN	$1		Y = Yes N = No		TEDYN
③ TEDDT	dd/MMM/yyyy				TEDDT
④ TEDTIM	HH:nn				TEDTIM
⑤ TEDTIMUN	1				TEDTIMUN
⑥ TEDRESC	$2		1 = Systemic corticosteroids 2 = Teprotumumab 3 = Orbital decompression 4 = Orbital irradiation 99 = Other		TEDRESC
⑦ TEDOTH	$200				TEDOTH
⑧ TEDEYE	$1		1 = Right Eye (OD) 2 = Left Eye (OS) 3 = Both Eyes (OU)		TEDEYE

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(9) TEDDET	1				TEDDET
(10) TEDDET1	1				TEDDET1
(11) TEDDET2	1				TEDDET2
(12) TEDADD	$200				TEDADD
(13) TEDRESO	$1		Y = Yes N = No		TEDRESO

Was the participants treatment unmasked?   Yes ◯ **①**
                                                                  No ◯

If Yes, specify reason   _____ **②**

Date of unmasking (DD MMM YYYY)   _____ **③**

Unmasking performed by   Sponsor ◯ **④**
                                               Investigators ◯
                                              Site personnel ◯

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① DTYN	$2		Y = Yes N = No		DTYN
② DTREAS	$200				DTREAS
③ DTDAT	dd/MMM/yy yy				DTDAT
④ DTUNMASK	$2		1 = Sponsor 2 = Investigators 3 = Site personnel		DTUNMASK

Date of Death _____ ①

Primary cause of death

Adverse Event ◯ ②
Unknown ◯
Other ◯

If Adverse Event, specify [Dynamic Search List] _____ ③

If Other, please specify _____ ④

Was an autopsy performed?

Yes ◯ ⑤
No ◯
Unknown ◯

If Yes, specify results _____ ⑥

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① DTHDT	dd/MMM/yy yy				DTHDT
② DTHREAS	$2		1 = Adverse Event 92 = Unknown 99 = Other		DTHREAS
③ DTHDSLAE	$200				DTHDSLAE
④ DTHOTH	$200				DTHOTH
⑤ DTHAUTYN	$2		Y = Yes N = No UN = Unknown		DTHAUTYN
⑥ DTHSPEC	$200				DTHSPEC

Date of Assessment (DD/MMM/YYYY) _____ ①

Result   Normal ◯ ②
                                  Abnormal, clinically ◯
                                           significant
                             Abnormal, not clinically ◯
                                           significant

If Abnormal - Was there any evidence for active   Yes ◯ ③
tuberculosis or other infection?   No ◯

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① XRDAT	dd/MMM/yy yy				XRDAT
② XRRES	$2		1 = Normal 2 = Abnormal, clinically significant 3 = Abnormal, not clinically significant		XRRES
③ XRINFEC	$2		Y = Yes N = No		XRINFEC

Were all components of the exam completed?   Yes ⃝ ①
                                                              No ⃝

If no, provide reason   _____ ②

Date of Assessment (DD/MMM/YYYY)   _____ ③

Time of Assessment (24 HR)   _____ ④

BCVA

Unit of Measurement   Feet ⃝ ⑥
                                             Meters ⃝

Snellen Acuity Numerator - OD   _____ ⑦

Snellen Acuity Denominator - OD   _____ ⑧

For BCVA less than 20/400 or equivalent for OD, please   ⑨
specify. See Study Operations Manual for more details. _____

Snellen Acuity Numerator - OS   _____ ⑩

Snellen Acuity Denominator - OS   _____ ⑪

For BCVA less than 20/400 or equivalent for OS, please   ⑫
specify. See Study Operations Manual for more details. _____

REFRACTION - RIGHT EYE (OD)

Not Assessed _____ 14

Sphere   + ◯ 15
       - ◯
      PL ◯

_____ 16

Cylinder   + ◯ 17
       - ◯

_____ 18

N/A _____ 19

Axis (Degrees) - OD _____ 20

N/A _____ 21

REFRACTION - LEFT EYE (OS)

Not Assessed _____ 23

Sphere   + ◯ 24
       - ◯
      PL ◯

_____ 25

Cylinder
+ ◯ **26**
- ◯

27

N/A
28

Axis (Degrees) - OS
29

N/A
30

EXTERNAL

Eyelids

Not Assessed
33

Eyelid Swelling that is considered to be due to active (inflammatory phase) TED (CAS) - OD
0=Absent ◯ **34**
1=Present ◯

Eyelid erythema (CAS) - OD
0=Absent ◯ **35**
1=Present ◯

Palpebral aperture (mm) - OD-OBSOLETE
36

Palpebral aperture (mm) - OD (Derived)
37

Upper lid retraction (MRD1) (mm) - OD
38

Lower lid retraction (MRD2) (mm)– OD _____ **39**

Eyelid Swelling that is considered to be due to active (inflammatory phase) TED (CAS) - OS

0=Absent ◯ **40**
1=Present ◯

Eyelid erythema (CAS) - OS

0=Absent ◯ **41**
1=Present ◯

Palpebral aperture (mm) - OS-OBSOLETE _____ **42**

Palpebral aperture (mm) - OS (Derived) _____ **43**

Upper lid retraction (MRD1) (mm) - OS _____ **44**

Lower lid retraction (MRD2) (mm) - OS _____ **45**

Proptosis (mm)

Not Assessed _____ **47**

Exophthalmometer reading (Hertel value (mm)) - OD _____ **48**

Exophthalmometer reading (Hertel value (mm)) - OS _____ **49**

Distance between lateral rims (mm) _____ **50**

Exophthalmometer ID (Hertel exophthalmometer identifier) _____ **51**

Evaluator Initials _____ 52

Monocular Ductions (Degrees)

Not Assessed _____ 54

Adduction - OD _____ 55

Abduction - OD _____ 56

Elevation (Supraduction) OD _____ 57

Depression (Infraduction) for OD _____ 58

Adduction - OS _____ 59

Abduction - OS _____ 60

Elevation (Supraduction) OS _____ 61

Depression (Infraduction) for OS _____ 62

Orbital Pain

Not Assessed _____ 64

Spontaneous orbital pain (CAS) - OD 0=Absent ◯ 65
1=Present ◯

Gaze evoked orbital pain (CAS) - OD

0=Absent ◯ **66**
1=Present ◯

Spontaneous orbital pain (CAS) - OS

0=Absent ◯ **67**
1=Present ◯

Gaze evoked orbital pain (CAS) - OS

0=Absent ◯ **68**
1=Present ◯

Ocular Alignment

Diplopia Score (Gorman)

Was Diplopia score done ?

Yes ◯ **70**
No ◯

Please select Diplopia score

No Diplopia (absent) (0) ◯ **71**
Diplopia when participant is ◯
tired or awakening
(intermittent) (1)
Diplopia at extremes of ◯
gaze (inconstant) (2)
Continuous Diplopia in the ◯
primary or reading position
(constant) (3)

Modified Gorman Diplopia Score

Was Modified Gorman Scale done?

Yes ◯ **73**
No ◯

NA ◯

Straight Ahead

No diplopia ◯ **74**
Intermittent diplopia ◯
Constant diplopia ◯

Left Gaze

No diplopia ◯ **75**
Intermittent diplopia ◯
Constant diplopia ◯

Right Gaze

No diplopia ◯ **76**
Intermittent diplopia ◯
Constant diplopia ◯

Upward Gaze

No diplopia ◯ **77**
Intermittent diplopia ◯
Constant diplopia ◯

Downward Gaze

No diplopia ◯ **78**
Intermittent diplopia ◯
Constant diplopia ◯

Observed

Not Assessed _____ **80**

Esotropia - OD

Yes ◯ **81**
No ◯

Exotropia - OD	Yes ☐ **82**	No ☐

Hypotropia - OD	Yes ☐ **83**	No ☐

Hypertropia - OD	Yes ☐ **84**	No ☐

Esotropia - OS	Yes ☐ **85**	No ☐

Exotropia - OS	Yes ☐ **86**	No ☐

Hypotropia - OS	Yes ☐ **87**	No ☐

Hypertropia - OS	Yes ☐ **88**	No ☐

Color Vision (Number of correct plates out of 38)

Not Assessed	_____ **90**

Right Eye (OD)	_____ **91**

Left Eye (OS)   **97**

Pupils

Not Assessed   **94**

| Is Afferent Pupillary Defect (APD) present? - OD | Yes ◯ **95** |
| | No ◯ |

| Are the pupils reactive to light? - OD | Yes ◯ **96** |
| | No ◯ |

| Is Afferent Pupillary Defect (APD) present? - OS | Yes ◯ **97** |
| | No ◯ |

| Are the pupils reactive to light? - OS | Yes ◯ **98** |
| | No ◯ |

Confrontational Visual Field

Is there a restriction in the visual field?

Not Assessed   **100**

| Nasal - OD | Yes ◯ **101** |
| | No ◯ |

Temporal - OD   Yes ☐ **102**
                                                        No ☐

Superior - OD   Yes ☐ **103**
                                                        No ☐

Inferior - OD   Yes ☐ **104**
                                                        No ☐

Superior Nasal - OD   Yes ☐ **105**
                                                        No ☐

Inferior Nasal - OD   Yes ☐ **106**
                                                        No ☐

Superior Temporal - OD   Yes ☐ **107**
                                                        No ☐

Inferior Temporal - OD   Yes ☐ **108**
                                                        No ☐

Nasal - OS   Yes ☐ **109**
                                                        No ☐

Temporal - OS   Yes ☐ **110**
                                                        No ☐

Superior - OS   Yes◯ **111**
                                  No◯

Inferior - OS   Yes◯ **112**
                                  No◯

Superior Nasal - OS   Yes◯ **113**
                                  No◯

Inferior Nasal - OS   Yes◯ **114**
                                  No◯

Superior Temporal - OS   Yes◯ **115**
                                  No◯

Inferior Temporal - OS   Yes◯ **116**
                                  No◯

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(1) OPYN	$2		Y = Yes N = No		OPYN
(2) OPREAS	$200				OPREAS
(3) OPDAT	dd/MMM/yy yy				OPDAT
(4) OPTIM	HH:nn				OPTIM
(6) OPSUNIT	$1		1 = Feet 2 = Meters		OPSUNIT
(7) OPSNOD1	2				OPSNOD1
(8) OPSNOD2	7.2				OPSNOD2
(9) OPSBCVA	$200				OPSBCVA
(10) OPSNOS1	2				OPSNOS1
(11) OPSNOS2	7.2				OPSNOS2
(12) OPSBCVA1	$200				OPSBCVA1
(14) RREODNA	1				RREODNA

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15 OPSHOD	$1		1 = + 2 = - 3 = PL		OPSHOD
16 OPSHODCO	4.2				OPSHODCO
17 OPCYOD	$1		1 = + 2 = -		OPCYOD
18 OPCYODCO	4.2				OPCYODCO
19 OPXNA3	1				OPXNA3
20 OPAXISOD	5				OPAXISOD
21 OPXNA	1				OPXNA
23 RLEOSNA	1				RLEOSNA
24 OPSHOS	$1		1 = + 2 = - 3 = PL		OPSHOS
25 OPSHOSCO	4.2				OPSHOSCO
26 OPCYOS	$1		1 = + 2 = -		OPCYOS

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
27	OPCYOSCO	4.2				OPCYOSCO
28	OPXNA4	1				OPXNA4
29	OPAXISOS	5				OPAXISOS
30	OPXNA2	1				OPXNA2
33	EYELDNA	1				EYELDNA
34	OPSWOD	$1		1 = 0=Absent 2 = 1=Present		OPSWOD
35	OPETHOD	$1		1 = 0=Absent 2 = 1=Present		OPETHOD
36	OPPALOD	3.1				OPPALOD
37	Z_OPPALOD1	3.1				Z_OPPALOD1
38	OPLIDOD	3.1				OPLIDOD
39	OPLIDOD1	3.1				OPLIDOD1

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
40	OPSWOS	$1		1 = 0=Absent 2 = 1=Present		OPSWOS
41	OPETHOS	$1		1 = 0=Absent 2 = 1=Present		OPETHOS
42	OPPALOS	3.1				OPPALOS
43	Z_OPPALOS 1	3.1				Z_OPPALOS 1
44	OPLIDOS	3.1				OPLIDOS
45	OPLIDOS1	3.1				OPLIDOS1
47	PROPNA	1				PROPNA
48	OPEXOD	3.1				OPEXOD
49	OPEXOS	3.1				OPEXOS
50	OPINT	4.1				OPINT
51	OPEX	$10				OPEX

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
52 OPEV	$5				OPEV
54 MDNA	1				MDNA
55 OPADOD	5.2				OPADOD
56 OPBOD	5.2				OPBOD
57 OPDEGOD	5.2				OPDEGOD
58 OPINFROD	5.2				OPINFROD
59 OPADOS	5.2				OPADOS
60 OPBOS	5.2				OPBOS
61 OPDEGOS	5.2				OPDEGOS
62 OPINFROS	5.2				OPINFROS
64 OBPNA	1				OBPNA
65 OPSPONOD	$1		1 = 0=Absent 2 = 1=Present		OPSPONOD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
66	OPGZOD	$1		1 = 0=Absent 2 = 1=Present		OPGZOD
67	OPSPONOS	$1		1 = 0=Absent 2 = 1=Present		OPSPONOS
68	OPGZOS	$1		1 = 0=Absent 2 = 1=Present		OPGZOS
70	OPDIPSC	$1		Y = Yes N = No		OPDIPSC
71	OPDIP	$1		1 = No Diplopia (absent) (0) 2 = Diplopia when participant is tired or awakening (intermittent) (1)		OPDIP

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Diplopia at extremes of gaze (inconstant) (2) 4 = Continuous Diplopia in the primary or reading position (constant) (3)		
73 OPMGSYN	$2		Y = Yes N = No NA = NA		OPMGSYN
74 MGSSA	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSSA
75 MGSLG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSLG

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
76	MGSRG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSRG
77	MGSUG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSUG
78	MGSDG	1		0 = No diplopia 1 = Intermittent diplopia 2 = Constant diplopia		MGSDG
80	OBSVNA	1				OBSVNA
81	OPESOD	$1		Y = Yes N = No		OPESOD
82	OPXOOD	$1		Y = Yes		OPXOOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			N = No		
83 OPHYOD	$1		Y = Yes N = No		OPHYOD
84 OPPIAOD	$1		Y = Yes N = No		OPPIAOD
85 OPESOS	$1		Y = Yes N = No		OPESOS
86 OPXOOS	$1		Y = Yes N = No		OPXOOS
87 OPHYOS	$1		Y = Yes N = No		OPHYOS
88 OPPIAOS	$1		Y = Yes N = No		OPPIAOS
90 CVNA	1				CVNA
91 OPCVOD	2				OPCVOD
92 OPCVOS	2				OPCVOS
94 PUPNA	1				PUPNA

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
95	OPAPDOD	$1		Y = Yes N = No		OPAPDOD
96	OPLGHOD	$1		Y = Yes N = No		OPLGHOD
97	OPAPDOS	$1		Y = Yes N = No		OPAPDOS
98	OPLGHOS	$1		Y = Yes N = No		OPLGHOS
100	CONFNA	1				CONFNA
101	OPNAOD	$1		Y = Yes N = No		OPNAOD
102	OPTEMOD	$1		Y = Yes N = No		OPTEMOD
103	OPSSOD	$1		Y = Yes N = No		OPSSOD
104	OPSIOD	$1		Y = Yes N = No		OPSIOD
105	OPSNOD	$1		Y = Yes N = No		OPSNOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
106 OPINOD	$1		Y = Yes N = No		OPINOD
107 OPSTOD	$1		Y = Yes N = No		OPSTOD
108 POITOD	$1		Y = Yes N = No		POITOD
109 OPNAOS	$1		Y = Yes N = No		OPNAOS
110 OPTEMOS	$1		Y = Yes N = No		OPTEMOS
111 OPSSOS	$1		Y = Yes N = No		OPSSOS
112 OPSIOS	$1		Y = Yes N = No		OPSIOS
113 OPSNOS	$1		Y = Yes N = No		OPSNOS
114 OPINOS	$1		Y = Yes N = No		OPINOS
115 OPSTOS	$1		Y = Yes N = No		OPSTOS

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(116) POITOS	$1		Y = Yes N = No		POITOS

Were all components of the exam completed?　Yes ◯ ①
　No ◯

If no, provide reason　_____ ②

Date of Assessment (DD/MMM/YYYY)　_____ ③

Time of Assessment (24 HR)　_____ ④

Conjunctiva

Not Assessed　_____ ⑥

Conjunctival redness that is considered to be due to active (inflammatory phase) TED (CAS) - OD　0=Absent ◯ ⑦
1=Present ◯

Chemosis (CAS) - OD　0=Absent ◯ ⑧
1=Present ◯

If there are other abnormalities, please specify - OD　_____ ⑨

Conjunctival redness that is considered to be due to active (inflammatory phase) TED (CAS) - OS　0=Absent ◯ ⑩
1=Present ◯

Chemosis (CAS) - OS　0=Absent ◯ ⑪
1=Present ◯

If there are other abnormalities, please specify - OS　_____ ⑫

Plica

Not Assessed (14)

Inflammation of caruncle or plica (CAS) - OD   0=Absent ◯ (15)
                                                  1=Present ◯

If there are other abnormalities, please specify - OD   (16)

Inflammation of caruncle or plica (CAS) - OS   0=Absent ◯ (17)
                                                  1=Present ◯

If there are other abnormalities, please specify - OS   (18)

Cornea

Not Assessed (20)

Clear - OD   Yes ◯ (21)
                No ◯

Superficial Punctate Keratitis - OD   Yes ◯ (22)
                                         No ◯

Ulcer - OD   Yes ◯ (23)
                No ◯

If there are other abnormalities, please specify - OD   (24)

Clear - OS   Yes ◯ **25**
                                                No ◯

Superficial Punctate Keratitis - OS   Yes ◯ **26**
                                                No ◯

Ulcer - OS   Yes ◯ **27**
                                                No ◯

If there are other abnormalities, please specify - OS   _____ **28**

Anterior Chamber

Not Assessed   _____ **30**

Clear - OD   Yes ◯ **31**
                                                No ◯

Deep - OD   Yes ◯ **32**
                                                No ◯

If abnormal, please specify - OD   _____ **33**

Clear - OS   Yes ◯ **34**
                                                No ◯

Deep - OS   Yes ◯ **35**

No◯

If abnormal, please specify - OS _____ **36**

Iris

Not Assessed _____ **38**

Normal - OD Yes◯ **39**
No◯

If Abnormal, please specify - OD _____ **40**

Normal - OS Yes◯ **41**
No◯

If Abnormal, please specify - OS _____ **42**

Lens

Not Assessed _____ **44**

Lens - OD Normal phakic◯ **45**
Abnormal phakic◯
Pseudophakic◯
Aphakic◯

If Abnormal phakic, check all that apply - OD

Cataract nuclear _____ (47)

Cataract cortical _____ (48)

Cataract posterior subcapsular _____ (49)

Other _____ (50)

If Other, please describe _____ (51)

If Abnormal phakic, has there been any progression of cataract since screening? - OD
Yes ◯ (52)
No ◯

If Yes, please describe _____ (53)

If Pseudophakic, please select - OD
Posterior chamber lens ◯ (54)
Anterior chamber lens ◯
Other ◯

If Other, please specify _____ (55)

Lens - OS
Normal phakic ◯ (56)
Abnormal phakic ◯
Pseudophakic ◯
Aphakic ◯

If Abnormal phakic, check all that apply - OS

Cataract nuclear _____ (58)

Cataract cortical _____ (59)

Cataract posterior subcapsular _____ (60)

Other _____ (61)

If Other, please describe _____ (62)

If Abnormal phakic, has there been any progression of cataract since screening? - OS   Yes ⬜ (63)   No ⬜

If Yes, please describe _____ (64)

If Pseudophakic, please select - OS   Posterior chamber lens ⬜ (65)   Anterior chamber lens ⬜   Other ⬜

If Other, please specify _____ (66)

IOP

Not Assessed _____ (68)

mmHg - OD _____ (69)

mmHg - OS _____ (70)

Method   Tonopen ◯ **71**
                                        Goldmann tonometry ◯
                                                         Other ◯

If Other, please specify   _____ **72**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① OPYN	$2		Y = Yes N = No		OPYN
② OPREAS	$200				OPREAS
③ OPDAT	dd/MMM/yyyy				OPDAT
④ OPTIM	HH:nn				OPTIM
⑥ OPCONA	1				OPCONA
⑦ OPCONOD	$1		1 = 0=Absent 2 = 1=Present		OPCONOD
⑧ OPCHOD	$1		1 = 0=Absent 2 = 1=Present		OPCHOD
⑨ OPCSPOD	$200				OPCSPOD
⑩ OPCONOS	$1		1 = 0=Absent 2 = 1=Present		OPCONOS

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(11) OPCHOS	$1		1 = 0=Absent 2 = 1=Present		OPCHOS
(12) OPCSPOS	$200				OPCSPOS
(14) OPPLINA	1				OPPLINA
(15) OPPLIOD	$1		1 = 0=Absent 2 = 1=Present		OPPLIOD
(16) OPPLSPOD	$200				OPPLSPOD
(17) OPPLIOS	$1		1 = 0=Absent 2 = 1=Present		OPPLIOS
(18) OPPLSPOS	$200				OPPLSPOS
(20) OPCLODNA	1				OPCLODNA
(21) OPCLOD	$1		Y = Yes N = No		OPCLOD
(22) OPSUOD	$1		Y = Yes		OPSUOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			N = No		
23 OPULOD	$1		Y = Yes N = No		OPULOD
24 OPSPEC3	$200				OPSPEC3
25 OPCLOS	$1		Y = Yes N = No		OPCLOS
26 OPSUOS	$1		Y = Yes N = No		OPSUOS
27 OPULOS	$1		Y = Yes N = No		OPULOS
28 OPSPEC9	$200				OPSPEC9
30 OPCODNA	1				OPCODNA
31 OPCOD	$1		Y = Yes N = No		OPCOD
32 OPDOD	$1		Y = Yes N = No		OPDOD
33 OPSPEC4	$200				OPSPEC4

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(34) OPCOS	$1		Y = Yes N = No		OPCOS
(35) OPDOS	$1		Y = Yes N = No		OPDOS
(36) OPSPEC11	$200				OPSPEC11
(38) OPIODNA	1				OPIODNA
(39) OPIOD	$1		Y = Yes N = No		OPIOD
(40) OPSPEC5	$200				OPSPEC5
(41) OPIOS	$1		Y = Yes N = No		OPIOS
(42) OPSPEC10	$200				OPSPEC10
(44) OPHODNA	1				OPHODNA
(45) OPLENSOD	$1		1 = Normal phakic 2 = Abnormal phakic		OPLENSOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Pseudophakic 4 = Aphakic		
(47) OPCATOD	1				OPCATOD
(48) OPCCOD	1				OPCCOD
(49) OPPSOD	1				OPPSOD
(50) OPOTH2	1				OPOTH2
(51) OPSPEC14	$200				OPSPEC14
(52) OPKOD	$1		Y = Yes N = No		OPKOD
(53) OPSPEC6	$200				OPSPEC6
(54) OPPOOD	$1		1 = Posterior chamber lens 2 = Anterior chamber lens		OPPOOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Other		
55 OPSPEC12	$200				OPSPEC12
56 OPLENSOS	$1		1 = Normal phakic 2 = Abnormal phakic 3 = Pseudophakic 4 = Aphakic		OPLENSOS
58 OPCATOS	1				OPCATOS
59 OPCCOS	1				OPCCOS
60 OPPSOS	1				OPPSOS
61 OPOTH	1				OPOTH
62 OPSPEC13	$200				OPSPEC13
63 OPKKOS	$1		Y = Yes N = No		OPKKOS
64 OPSPEC7	$200				OPSPEC7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
65	OPPOOS	$1		1 = Posterior chamber lens 2 = Anterior chamber lens 3 = Other		OPPOOS
66	OPSPEC8	$200				OPSPEC8
68	OPMGNA	1				OPMGNA
69	OPMMGOD	3.1				OPMMGOD
70	OPMMGOS	3.1				OPMMGOS
71	OPMETH	$1		1 = Tonopen 2 = Goldmann tonometry 3 = Other		OPMETH
72	OPMETOTH	$200				OPMETOTH

Were all components of the exam completed? Yes◯ **①**
No◯

If no, provide reason _____ **②**

Date performed (DD/MMM/YYYY) _____ **③**

Time of Assessment (24 HR) _____ **④**

Vitreous

Not Assessed _____ **⑥**

OD Normal◯ **⑦**
Abnormal◯

If abnormal, please specify - OD _____ **⑧**

OS Normal◯ **⑨**
Abnormal◯

If abnormal, please specify - OS _____ **⑩**

Optic Nerve

Not Assessed _____ **⑫**

Optic Nerve Normal - OD Yes◯ **⑬**

No◯

Optic Nerve Pallor - OD | Yes◯ **14**
No◯

Optic Nerve Swelling - OD | Yes◯ **15**
No◯

If there are other abnormalities, please specify - OD | _____ **16**

Optic Nerve Cup to Disc (C/D) - OD | _____ **17**

Optic Nerve Normal - OS | Yes◯ **18**
No◯

Optic Nerve Pallor - OS | Yes◯ **19**
No◯

Optic Nerve Swelling - OS | Yes◯ **20**
No◯

If there are other abnormalities, please specify - OS | _____ **21**

Optic Nerve Cup to Disc (C/D) - OS | _____ **22**

Macula

Not Assessed _____ (24)

OD Normal ◯ (25)
Abnormal ◯

If abnormal, please specify - OD _____ (26)

OS Normal ◯ (27)
Abnormal ◯

If abnormal, please specify - OS _____ (28)

Retinal Vessels

Not Assessed _____ (30)

OD Normal ◯ (31)
Abnormal ◯

If abnormal, please specify - OD _____ (32)

OS Normal ◯ (33)
Abnormal ◯

If abnormal, please specify - OS _____ (34)

Peripheral Retina

Not Assessed _____ **36**

OD   Normal ◯ **37**
                                                            Abnormal ◯

If abnormal, please specify - OD _____ **38**

OS   Normal ◯ **39**
                                                            Abnormal ◯

If abnormal, please specify - OS _____ **40**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	OPYN	$2		Y = Yes N = No		OPYN
2	OPREAS	$200				OPREAS
3	OPDAT	dd/MMM/yyyy				OPDAT
4	OPTIM	HH:nn				OPTIM
6	OPODNA	1				OPODNA
7	OPOD	$1		1 = Normal 2 = Abnormal		OPOD
8	OPODSP	$200				OPODSP
9	OPOS	$1		1 = Normal 2 = Abnormal		OPOS
10	OPOSSP	$200				OPOSSP
12	OPNODNA	1				OPNODNA
13	OPNOD	$1		Y = Yes N = No		OPNOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
14 OPPOD	$1		Y = Yes N = No		OPPOD
15 OPSOD	$1		Y = Yes N = No		OPSOD
16 OPSPEC1	$200				OPSPEC1
17 OPNCOD	4.2				OPNCOD
18 OPNOS	$1		Y = Yes N = No		OPNOS
19 OPPOS	$1		Y = Yes N = No		OPPOS
20 OPSOS	$1		Y = Yes N = No		OPSOS
21 OPSOSPEC	$200				OPSOSPEC
22 OPNCOS	4.2				OPNCOS
24 OPMODNA	1				OPMODNA
25 OPMOD	$1		1 = Normal 2 = Abnormal		OPMOD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
26	OPSPEC	$200				OPSPEC
27	OPMOS	$1		1 = Normal 2 = Abnormal		OPMOS
28	OPSPEC2	$200				OPSPEC2
30	OPRODNA	1				OPRODNA
31	OPROD	$1		1 = Normal 2 = Abnormal		OPROD
32	OPSSPEC5	$200				OPSSPEC5
33	OPROS	$1		1 = Normal 2 = Abnormal		OPROS
34	OPSPEC3	$200				OPSPEC3
36	OPPRODNA	1				OPPRODNA
37	OPPROD	$1		1 = Normal 2 = Abnormal		OPPROD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
38	OPSSPEC6	$200				OPSSPEC6
39	OPPROS	$1		1 = Normal 2 = Abnormal		OPPROS
40	OPSPEC4	$200				OPSPEC4

Only participants who are proptosis non-responders and without any rescue therapy/intervention received during
Period A (Primary Efficacy Period), will be administered TOUR006 50 mg SC on Weeks 24, 32, and 40.

Did the participant receive any rescue treatment or intervention during Period A?

Yes ◯ ②
No ◯

Did the participant have a ≥2 mm proptosis reduction from baseline in the study eye
without deterioration [≥2 mm increase] of proptosis in the fellow eye in Period A?

Yes ◯ ③
No ◯

Baseline Measurements
Exophthalmometer reading (Hertel value (mm)) (Derived from Ocular Exam Day 1)

Study Eye _____ ⑤

Fellow Eye _____ ⑥

Week 24 Measurements

Exophthalmometer reading (Hertel value (mm))
(Derived from Ocular
Exam Week 24)

Study Eye _____ ⑧

Change from baseline (mm) (auto calculation) _____ ⑨

Fellow Eye _____ ⑩

Change from baseline (mm) (auto calculation) _____ ⑪

Will Participant receive study drug administrations in Period B?
(Sent to RTSM)

Receive Study Drug ◯ ⑫
Not Receive Study Drug ◯

RTSM Treatment Period (Sent to RTSM) [Derived]

Period A ◯ ⑬
Period B ⬤

RTSM Cohort Re-evaluation field (Sent to RTSM) [Hidden]

true ⬤ ⑭
false ◯

Date participant enters Period B (DD/MMM/YYYY) (Received from RTSM) [Hidden] _____ ⑮

Time participant enters Period B (24 HR) (Received from RTSM) [Hidden] _____ ⑯

Randomization Date and Time (Received from RTSM) [Hidden] _____ ⑰

Kit Number (Received from RTSM) [Hidden] _____ ⑱

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
②	OPRES	$1		Y = Yes N = No		OPRES
③	OPRED	$1		Y = Yes N = No		OPRED
⑤	OPBAS	3.1				OPBAS
⑥	OPBAS2	3.1				OPBAS2
⑧	OPBAS3	3.1				OPBAS3
⑨	OPBAS5	3.1				OPBAS5
⑩	OPBAS4	3.1				OPBAS4
⑪	OPBAS6	3.1				OPBAS6
⑫	OPPARB	$1		1 = Receive Study Drug 2 = Not Receive Study Drug		OPPARB
⑬	Period	$1		1 = Period A 2 = Period B		RNPERIOD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(14)	cohortReEvaluate	1		1 = true 2 = false		COHREVAL
(15)	OPDATB	dd/MMM/yyyy				OPDATB
(16)	OPTMB	HH:nn				OPTMB
(17)	RANDOMIZED_AT	dd/MMM/yyyy HH:nn:ss				RANDOMIZED_AT
(18)	ITEMS	$30				ITEMS

Was pregnancy test performed?   Yes ⬭ ①
                                                                            No ⬭

If No, please provide reason   _____ ②

Sample collection date (DD/MMM/YYYY)   _____ ③

Sample collection time (24 HR)   _____ ④

Result   Positive ⬭ ⑤
                                                    Negative ⬭

Confirmed positive pregnancy results must be recorded on the Pregnancy Reporting
Form.

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PREGYN	$1		Y = Yes N = No		PREGYN
② PGREAS	$200				PGREAS
③ PREGDAT	dd/MMM/yyyy				PREGDAT
④ PREGTIM	HH:nn				PREGTIM
⑤ PREGRES	$2		1 = Positive 2 = Negative		PREGRES

Was a sample collected?   Yes ◯ **1**
                                                        No ◯

If No, please provide reason   _____ **2**

Date of Sample Collection (DD/MMM/YYYY)   _____ **3**

Time of Sample Collection (24 HR)   _____ **4**

Was the sample sent to the Laboratory?   Yes ◯ **5**
                                                     No ◯

If No, please provide reason   _____ **6**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yyyy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ◯ **1**
                                                                No ◯

If No, please provide reason   _____ **2**

Date of Sample Collection (DD/MMM/YYYY)   _____ **3**

Time of Sample Collection (24 Hr)   _____ **4**

Was the sample sent to the Laboratory?   Yes ◯ **5**
                                                                No ◯

If No, please provide reason   _____ **6**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBYN	$1		Y = Yes N = No		LBYN
② LBREAS	$200				LBREAS
③ LBDATE	dd/MMM/yy yy				LBDATE
④ LBTIM	HH:nn				LBTIM
⑤ LBSENT	$1		Y = Yes N = No		LBSENT
⑥ LBREAS2	$200				LBREAS2

Was a sample collected?   Yes ◯ **1**
                                                                No ◯

If No, please provide reason   _____ **2**

Date of Sample Collection (DD/MMM/YYYY)   _____ **3**

Time of Sample Collection (24 HR)   _____ **4**

Was the sample sent to the Laboratory?   Yes ◯ **5**
                                                                 No ◯

If No, please provide reason   _____ **6**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yyyy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

SERUM hs-CRP

Was a sample collected?   Yes ⃝ ②
                                                            No ⃝

If No, please provide reason   _____ ③

Date of Sample Collection (DD/MMM/YYYY) _____ ④

Time of Sample Collection (24 HR)   _____ ⑤

Was the sample sent to the Laboratory?   Yes ⃝ ⑥
                                                            No ⃝

If No, please provide reason   _____ ⑦

IL-6

Was a sample collected?   Yes ⃝ ⑨
                                                            No ⃝

If No, please provide reason   _____ ⑩

Date of Sample Collection (DD/MMM/YYYY) _____ ⑪

Time of Sample Collection (24 HR)   _____ ⑫

Was the sample sent to the Laboratory?   Yes ⃝ ⑬

No ⬭

If No, please provide reason _____ ⑭

Derived Date and Time _____ ⑮

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
2	LBYN	$1		Y = Yes N = No		LBYN
3	LBREAS	$200				LBREAS
4	LBDATE	dd/MMM/yyyy				LBDATE
5	LBTIM	HH:nn				LBTIM
6	LBSENT	$1		Y = Yes N = No		LBSENT
7	LBREAS2	$200				LBREAS2
9	LBYN2	$1		Y = Yes N = No		LBYN2
10	LBREAS3	$200				LBREAS3
11	LBDATE1	dd/MMM/yyyy				LBDATE1
12	LBTIM1	HH:nn				LBTIM1
13	LBSENT2	$1		Y = Yes N = No		LBSENT2

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(14) LBREAS4	$200				LBREAS4
(15) LBDTE1TM1	dd/MMM/yyyy HH:nn				LBDTE1TM1

Was a sample collected?   Yes◯**①**
                                                             No◯

If No, please provide reason   _____**②**

Date of sample Collection (DD/MMM/YYYY)   _____**③**

Time of sample Collection (24 Hr)   _____**④**

Was the sample sent to the Laboratory?   Yes◯**⑤**
                                                             No◯

If No, please provide the reason   _____**⑥**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBYN	$1		Y = Yes N = No		LBYN
2	LBREAS	$200				LBREAS
3	LBDATE	dd/MMM/yyyy				LBDATE
4	LBTIM	HH:nn				LBTIM
5	LBSENT	$1		Y = Yes N = No		LBSENT
6	LBREAS2	$200				LBREAS2

Do you wish to assign study drug to the participant?
(Sent to RTSM)

Yes ◯ ①
No ◯

RTSM Treatment Period (Sent to RTSM) [Hidden]

Period A ◯ ②
Period B ◯

Date of Dispense (DD/MMM/YYYY) (Received from
RTSM)

③
_____

Kit Number (Received from RTSM)

④
_____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	SDDYN	$1		Y = Yes N = No		SDDYN
2	Period	$1		1 = Period A 2 = Period B		RNPERIOD
3	SDDDAT	dd/MMM/yy yy				SDDDAT
4	ITEMS	$30				ITEMS

Was study drug administered?   Yes ⃝ ①
                                                                No ⃝

If No, please specify the reason   _____ ②

Date of Study Drug Administration (DD/MMM/YYYY)   _____ ③

Time of Study Drug Administration (24 HR)   _____ ④

Route   Subcutaneous Injection ⑤

Injection Site Body location   Left thigh ⃝ ⑥
                                                     Right thigh ⃝

Planned volume   _____ ⑦

Actual volume administered (mL)   _____ ⑧

Was study drug administered as planned?   Yes ⃝ ⑨
                                                                No ⃝

If No, please specify   _____ ⑩

Please ensure any injection site reactions are captured on the AE page.

Date and Time Derivation   _____ ⑫

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	EXPERF	$1		Y = Yes N = No		EXPERF
2	EXREAS	$200				EXREAS
3	EXDT	dd/MMM/yy yy				EXDT
4	EXTM	HH:nn				EXTM
5	EXROUTE	$22		Subcutaneo us Injection		EXROUTE
6	EXLOC	$1		1 = Left thigh 2 = Right thigh		EXLOC
7	EXVOL	$6				EXVOL
8	EXACVOL	5.2				EXACVOL
9	EXPERF1	$1		Y = Yes N = No		EXPERF1
10	EXREAS1	$200				EXREAS1

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑰ EXDTTIME	dd/MMM/yy yy HH:nn				EXDTTIME

Was contact successful?   Yes ⃝ ①
                                                            No ⃝

If no, please specify the reason   _____ ②

Date of Contact (DD/MMM/YYYY)   _____ ③

Time of Contact (24 HR)   _____ ④

Did the participant experience any Adverse Event?   Yes ⃝ ⑤
                                                            No ⃝

If Yes, please select AE   ⑥
[Dynamic Search List]   _____

If Yes, please select AE   ⑦
[Dynamic Search List]   _____

If Yes, please select AE   ⑧
[Dynamic Search List]   _____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FUPYN	$1		Y = Yes N = No		FUPYN
2	FUPREAS	$200				FUPREAS
3	FUPDAT	dd/MMM/yyyy				FUPDAT
4	FUPTIM	HH:nn				FUPTIM
5	FUPAEYN	$1		Y = Yes N = No		FUPAEYN
6	FUPAEDSL1	$200				FUPAEDSL1
7	FUPAEDSL2	$200				FUPAEDSL2
8	FUPAEDSL3	$200				FUPAEDSL3

_____

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

LAB Age (Derived) _____ ③

Platelet count _____ ④

Red blood cell (RBC) count _____ ⑤

Mean corpuscular volume
(MCV) _____ ⑥

Mean corpuscular
hemoglobin (MCH) _____ ⑦

Reticulocytes (Abs) _____ ⑧

Reticulocytes (%) _____ ⑨

White blood cells _____ ⑩

Neutrophils (%) _____ ⑪

Lymphocytes (%) _____ ⑫

Monocytes (%) _____ ⑬

Eosinophils (%) _____ 14

Basophils (%) _____ 15

Neutrophils (Abs) _____ 16

Lymphocytes (Abs) _____ 17

Monocytes (Abs) _____ 18

Eosinophils (Abs) _____ 19

Basophils (Abs) _____ 20

Hemoglobin _____ 21

Hematocrit _____ 22

RDW _____ 23

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yy yy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBAGE	3				LBAGE
4	PLT	10.3				PLT
5	RBC	10.3				RBC
6	MCV	10.3				MCV
7	MCH	10.3				MCH
8	RETABS	10.3				RETABS
9	RETICE	10.3				RETICE
10	WBC	10.3				WBC
11	NEUTLE	10.3				NEUTLE
12	LYMPHLE	10.3				LYMPHLE

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑬ MONOLE	10.3				MONOLE
⑭ EOSLE	10.3				EOSLE
⑮ BASOLE	10.3				BASOLE
⑯ NEUT	10.3				NEUT
⑰ LYMPH	10.3				LYMPH
⑱ MONO	10.3				MONO
⑲ EOS	10.3				EOS
⑳ BASO	10.3				BASO
㉑ HGB	10.3				HGB
㉒ HCT	10.3				HCT
㉓ RDW	10.3				RDW

_____

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

Was the participant fasting prior to sample collection?   Yes ◯ ③
No ◯
Unknown ◯

LAB Age (Derived) _____ ④

Blood urea nitrogen (BUN) _____ ⑤

Urea _____ ⑥

Potassium _____ ⑦

Creatinine _____ ⑧

Sodium _____ ⑨

Calcium _____ ⑩

Glucose (fasting) _____ ⑪

Glucose (non-fasting) _____ ⑫

Aspartate aminotransferase (AST) ⑬
(SGOT) _____

_____

Alanine aminotransferase (ALT)
(SGPT)   _____ (14)

_____

Alkaline phosphatase   _____ (15)

_____

Total bilirubin   _____ (16)

_____

Direct bilirubin   _____ (17)

_____

Total protein   _____ (18)

_____

Chloride   _____ (19)

_____

Carbon Dioxide (Bicarbonate)   _____ (20)

_____

Magnesium   _____ (21)

_____

Albumin   _____ (22)

_____

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

_____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yyyy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBFST	$3		Y = Yes N = No UN = Unknown		LBFST
4	LBAGE	3				LBAGE
5	BUN	10.3				BUN
6	UREA	10.3				UREA
7	K	10.3				K
8	CREAT	10.3				CREAT
9	NA	10.3				NA
10	CA	10.3				CA
11	GLUCF	10.3				GLUCF

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
12	GLUC	10.3				GLUC
13	SGOT	10.3				SGOT
14	SGPT	10.3				SGPT
15	ALP	10.3				ALP
16	BILI_TL	10.3				BILI_TL
17	BILI_DR	10.3				BILI_DR
18	PROT_TL	10.3				PROT_TL
19	CL	10.3				CL
20	BICARB	10.3				BICARB
21	MG	10.3				MG
22	ALB	10.3				ALB

_____

Sample collection date (DD/MMM/YYYY) _____ (1)

Time of sample collection (24 HR) _____ (2)

LAB Age (Derived) _____ (3)

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

HIV antibody   Negative ◯ (5)
                                                     Positive ◯

Hepatitis B surface antigen (Quantitative) _____ (6)

Hepatitis B surface antigen (Qualitative)   Negative ◯ (7)
                                                     Positive ◯

Hepatitis B surface antibody   Negative ◯ (8)
                                                     Positive ◯
                                                Indeterminate ◯

Hepatitis C virus anti-body   Negative ◯ (9)
                                                     Positive ◯

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBDATE	dd/MMM/yyyy				LBDATE
②	LBTIM	HH:nn				LBTIM
③	LBAGE	3				LBAGE
⑤	HIV12AB	10.3		0 = Negative 1 = Positive		HIV12AB
⑥	HBSAG	10.3				HBSAG
⑦	HBSAGQL	10.3		0 = Negative 1 = Positive		HBSAGQL
⑧	HBSAB	10.3		0 = Negative 1 = Positive -1 = Indeterminate		HBSAB
⑨	HCAB	10.3		0 = Negative 1 = Positive		HCAB

Form: LOCAL LABORATORY URINALYSIS - Macroscopic Panel (Dipstick)
Generated On: 30 May 2025 22:31:51 (GMT)
Lab Name:

Sample collection date (DD/MMM/YYYY) ⓵

Time of sample collection (24 HR) ②

LAB Age (Derived) ③

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Glucose
Positive ⑤
Negative ◯
Inconclusive ◯

Protein
Positive ⑥
Negative ◯
Inconclusive ◯

Ketone bodies
Positive ⑦
Negative ◯
Inconclusive ◯

Blood
Positive ⑧
Negative ◯
Inconclusive ◯

pH ⑨

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: LOCAL LABORATORY URINALYSIS - Macroscopic Panel (Dipstick)
Generated On: 30 May 2025 22:31:51 (GMT)
Lab Name: _____

Specific gravity _____ (10)

Bilirubin
Positive ◯ (11)
Negative ◯
Inconclusive ◯

Urobilinogen _____ (12)

Nitrite
Positive ◯ (13)
Negative ◯
Inconclusive ◯

Leukocyte esterase
Positive ◯ (14)
Negative ◯
Inconclusive ◯

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yy yy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBAGE	3				LBAGE
5	UGLUC	10.3		1 = Positive 2 = Negative 3 = Inconclusive		UGLUC
6	UPROT	10.3		1 = Positive 2 = Negative 3 = Inconclusive		UPROT
7	UKET	10.3		1 = Positive 2 = Negative 3 = Inconclusive		UKET

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
(8) UNITR	10.3		1 = Positive 2 = Negative 3 = Inconclusive		UNITR
(9) UPH	10.3				UPH
(10) USPGRAV	10.3				USPGRAV
(11) UBILI	10.3		1 = Positive 2 = Negative 3 = Inconclusive		UBILI
(12) UROBIL	10.3				UROBIL
(13) NITRITE	10.3		1 = Positive 2 = Negative 3 = Inconclusive		NITRITE
(14) LEUKASE	10.3		1 = Positive 2 = Negative		LEUKASE

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Inconclusive		

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

LAB Age (Derived) _____ ③

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Bacteria _____ ⑤

Granular Casts _____ ⑥

Hyaline Casts _____ ⑦

Mucus _____ ⑧

RBC _____ ⑨

RBC Casts _____ ⑩

Renal Epithelial Cells _____ ⑪

Squamous Epithelial
Cells _____ ⑫

Transitional Epithelial
Cells _____ ⑬

Waxy Casts   (14)

WBC   (15)

WBC Casts   (16)

Yeast   (17)

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yyyy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBAGE	3				LBAGE
5	BACT	$12				BACT
6	CSGRAN	$12				CSGRAN
7	CSHYAL	$12				CSHYAL
8	MUCUS	$12				MUCUS
9	RBC	$12				RBC
10	CSRBC	$12				CSRBC
11	EPIRCE	$12				EPIRCE
12	EPISQCE	$12				EPISQCE
13	EPITCE	$12				EPITCE
14	CSWAX	$12				CSWAX

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15 WBC	$12				WBC
16 CSWBC	$12				CSWBC
17 YEAST	$12				YEAST

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

LAB Age (Derived) _____ ③

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Free triiodothyronine
(FT3) _____ ⑤

Free thyroxine (FT4) _____ ⑥

Thyroid stimulating
hormone (TSH) _____ ⑦

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yy yy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBAGE	3				LBAGE
5	T3FR	10.3				T3FR
6	T4FR	10.3				T4FR
7	TSH	10.3				TSH

Project Name: TOUR006-T01
Form: LOCAL LABORATORY LIPID PANEL
Generated On: 30 May 2025 22:31:51 (GMT)
Lab Name: _____

_____

Sample collection date (DD/MMM/YYYY)   _____ ①

Time of sample collection (24 HR)   _____ ②

Was the participant fasting prior to sample collection?   Yes ◯ ③
No ◯
Unknown ◯

LAB Age (Derived)   _____ ④

Total cholesterol (fasting)   _____ ⑤

Total cholesterol (non-fasting)   _____ ⑥

Low-density lipoproteins (Direct) (fasting)   _____ ⑦

Low-density lipoproteins (Direct) (non-fasting)   _____ ⑧

High density lipoproteins (fasting)   _____ ⑨

High density lipoproteins (non-fasting)   _____ ⑩

Triglycerides (fasting)   _____ ⑪

Triglycerides (non-fasting)   _____ ⑫

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yy yy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBFST	$3		Y = Yes N = No UN = Unknown		LBFST
4	LBAGE	3				LBAGE
5	HDLCCHOL	10.3				HDLCCHOL
6	TCHOLNF	10.3				TCHOLNF
7	IDLPL	10.3				IDLPL
8	LDLCHLNF	10.3				LDLCHLNF
9	IDLPH	10.3				IDLPH
10	HDLCHLNF	10.3				HDLCHLNF
11	TRIG	10.3				TRIG

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
TRIGNF	10.3				TRIGNF

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: LOCAL LABORATORY COAGULATION PANEL
Generated On: 30 May 2025 22:31:51 (GMT)
Lab Name:

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

LAB Age (Derived) _____ ③

INR _____ ④

PTT _____ ⑤

aPTT _____ ⑥

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yy yy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBAGE	3				LBAGE
4	INR	10.3				INR
5	PTT	10.3				PTT
6	aPTT	10.3				APTT

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: LOCAL LABORATORY TEST TUBERCULOSIS (IGRA)
Generated On: 30 May 2025 22:31:51 (GMT)

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

LAB Age (Derived) _____ ③

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Tuberculosis (IGRA)   Negative ◯ ⑤
                                                        Positive ◯
                                                   Indeterminate ◯

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBDATE	dd/MMM/yyyy				LBDATE
② LBTIM	HH:nn				LBTIM
③ LBAGE	3				LBAGE
⑤ MTBIGAAB	10.3		0 = Negative 1 = Positive -1 = Indeterminate		MTBIGAAB

_____

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

LAB Age (Derived) _____ ③

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Hemoglobin A1c (%) _____ ⑤

Hemoglobin A1c (IFCC) _____ ⑥

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBDATE	dd/MMM/yyyy				LBDATE
② LBTIM	HH:nn				LBTIM
③ LBAGE	3				LBAGE
⑤ HBA1CP	10.3				HBA1CP
⑥ HBA1CI	10.3				HBA1CI

_____

Sample collection date (DD/MMM/YYYY) _____ ①

Time of sample collection (24 HR) _____ ②

LAB Age (Derived) _____ ③

If any new clinically significant abnormality began or worsened please report it on the Adverse Events page.

Follicle-stimulating hormone (FSH) _____ ⑤

Estradiol _____ ⑥

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	LBDATE	dd/MMM/yy yy				LBDATE
2	LBTIM	HH:nn				LBTIM
3	LBAGE	3				LBAGE
5	FSH	10.3				FSH
6	ESTRAD	10.3				ESTRAD