

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.

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: PARTICIPANT ENROLLMENT
Generated On: 30 May 2025 22:31:51 (GMT)

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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: PARTICIPANT ENROLLMENT
Generated On: 30 May 2025 22:31:51 (GMT)

	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

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

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

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

	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

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

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

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

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

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

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 - OPTHALMOSCOPY	_____	39

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

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	UNSDATE	dd MMM YYYY				UNSDATE
②	UNSREAS	\$200				UNSREAS
④	UNXRUNS	1				UNXRUNS
⑤	UNSPREG	1				UNSPREG
⑥	UNSPREG2	1				UNSPREG2
⑦	UNSLHM	1				UNSLHM
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

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

	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

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

	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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: PRE-SCREENING INFORMED CONSENT
Generated On: 30 May 2025 22:31:51 (GMT)

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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: PRE-SCREENING INFORMED CONSENT
Generated On: 30 May 2025 22:31:51 (GMT)

	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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: INFORMED CONSENT
Generated On: 30 May 2025 22:31:51 (GMT)

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
(DD/MMM/YYYY)

_____ ⑦

Protocol version reconsented to

Version 1.0 ☐ ⑧
Version 2.0 ☐
Version 3.0 ☐

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: INFORMED CONSENT
Generated On: 30 May 2025 22:31:51 (GMT)

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
'(XXX-XXX-XXX)'

14

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: INFORMED CONSENT
Generated On: 30 May 2025 22:31:51 (GMT)

	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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: INFORMED CONSENT
Generated On: 30 May 2025 22:31:51 (GMT)

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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: INFORMED CONSENT
Generated On: 30 May 2025 22:31:51 (GMT)

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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: ELIGIBILITY CRITERIA SCREENING
Generated On: 30 May 2025 22:31:51 (GMT)

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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: ELIGIBILITY CRITERIA SCREENING
Generated On: 30 May 2025 22:31:51 (GMT)

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



V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: ELIGIBILITY CRITERIA SCREENING
Generated On: 30 May 2025 22:31:51 (GMT)

	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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: ELIGIBILITY CRITERIA SCREENING
Generated On: 30 May 2025 22:31:51 (GMT)

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/yy yy				IESFDAT

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: ELIGIBILITY CRITERIA DAY 1
Generated On: 30 May 2025 22:31:51 (GMT)

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
([Dynamic Search List](#))

⑦

If Other, please specify

⑧


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

⑨

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: ELIGIBILITY CRITERIA DAY 1
Generated On: 30 May 2025 22:31:51 (GMT)

	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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: ELIGIBILITY CRITERIA DAY 1
Generated On: 30 May 2025 22:31:51 (GMT)

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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: DEMOGRAPHICS
Generated On: 30 May 2025 22:31:51 (GMT)

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 the protocol? Yes ☐ ④
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

V5.000 PROD SLF 15MAY2025: Unique
Project Name: TOUR006-T01
Form: DEMOGRAPHICS
Generated On: 30 May 2025 22:31:51 (GMT)

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	