Table of Contents
Screening
- Visit Date
- ICF
- INCL/EXCL Criteria Summary
- Demographics
- Medical History
- Complete Physical Examination
- Height, Weight and BMI
- Serology Lab Evaluation
- Serum Pregnancy Test
- Vital Signs
- UDS and Alcohol Laboratory Evaluation
- Cotinine Evaluation
- Chemistry Laboratory Evaluation
- Hematology Laboratory Evaluation
- Urinalysis Laboratory Evaluation
- Endocrinology Evaluation
- ECG Test Results
- Female Contraceptive Method
- Tobacco Use

Day -1
- Visit Date
- Urine Pregnancy Test
- Vital Signs
- UDS and Alcohol Laboratory Evaluation
- Symptom Directed Physical Exam

Day 1
- Visit Date
- Randomization
- Part A - Usual Brand Dose Log
- Part A - VLN Dosing Log
- Part A - Nicorette Dosing Log
- Use Product Again - VAS

Day 2
- Visit Date
- Part A - Usual Brand Dose Log
- Part A - VLN Dosing Log
- Part A - Nicorette Dosing Log
- Use Product Again - VAS

- Day 3
  - Visit Date
  - Part A - Usual Brand Dose Log
  - Part A - VLN Dosing Log
  - Part A - Nicorette Dosing Log
  - Use Product Again - VAS
- Day 4
  - Visit Date
  - Randomization
  - Part B - Controlled Nicorette Dosing Log
  - Part B - Uncontrolled Nicorette Dosing Log
  - Part B - Controlled Usual Brand Dosing Log
  - Part B - Uncontrolled Usual Brand Dosing Log
  - Part B - Controlled VLN Dosing Log
  - Part B - Uncontrolled VLN Dosing Log
  - 1st Use - Tobacco/Nicotine Questionnaire
  - 2nd Use - Tobacco/Nicotine Questionnaire
  - 1st Use - Direct Effects of Product Questionnaire
  - 2nd Use - Direct Effects of Product Questionnaire
  - Use Product Again - VAS
  - 1st Use - PK Blood Sampling
  - 2nd Use - PK Blood Sampling
- Day 5
  - Visit Date
  - Part B - Controlled Nicorette Dosing Log
  - Part B - Uncontrolled Nicorette Dosing Log
  - Part B - Controlled Usual Brand Dosing Log
  - Part B - Uncontrolled Usual Brand Dosing Log
  - Part B - Controlled VLN Dosing Log
  - Part B - Uncontrolled VLN Dosing Log
  - 1st Use - Tobacco/Nicotine Questionnaire
  - 2nd Use - Tobacco/Nicotine Questionnaire
  - 1st Use - Direct Effects of Product Questionnaire
  - 2nd Use - Direct Effects of Product Questionnaire
  - Use Product Again - VAS
  - 1st Use - PK Blood Sampling
  - 2nd Use - PK Blood Sampling
- Day 6
  - Visit Date
  - Vital Signs

- Chemistry Laboratory Evaluation
- Hematology Laboratory Evaluation
- Urinalysis Laboratory Evaluation
- Symptom Directed Physical Exam
- Part B - Controlled Nicorette Dosing Log
- Part B - Uncontrolled Nicorette Dosing Log
- Part B - Controlled Usual Brand Dosing Log
- Part B - Uncontrolled Usual Brand Dosing Log
- Part B - Controlled VLN Dosing Log
- Part B - Uncontrolled VLN Dosing Log
- 1st Use - Tobacco/Nicotine Questionnaire
- 2nd Use - Tobacco/Nicotine Questionnaire
- 1st Use - Direct Effects of Product Questionnaire
- 2nd Use - Direct Effects of Product Questionnaire
- Use Product Again - VAS
- 1st Use - PK Blood Sampling
- 2nd Use - PK Blood Sampling
- ECG Test Results
- End of Study

Early Term

- Visit Date
- Vital Signs
- Chemistry Laboratory Evaluation
- Hematology Laboratory Evaluation
- Urinalysis Laboratory Evaluation
- Symptom Directed Physical Exam
- ECG Test Results
- End of Study

All Visits

- Adverse Events
- Concomitant Medications

Unscheduled Visit

- Complete Physical Examination
- Serology Lab Evaluation
- Serum Pregnancy Test
- Urine Pregnancy Test
- UDS and Alcohol Laboratory Evaluation
- Cotinine Evaluation
- Chemistry Laboratory Evaluation
- Hematology Laboratory Evaluation

Urinalysis Laboratory Evaluation
Symptom Directed Physical Exam
Endocrinology Evaluation
ECG Test Results
Unscheduled Vital Signs

DM=Demographics

DS=Disposition

CEG_P1_078

ICF at Screening

DSDECOD/DSTERM=INFORMED CONSENT OBTAINED

Was the most current IRB approved version of the Informed Consent signed by the subject? ○ Yes ○ No

[NOT SUBMITTED]

RFICDTC

	Date Subject Signed ICF: (Original signature) **[2]**	**ICF Version: [3]**	**ICF Version Date: [4]**
1			

More rows: 1 5 10

DSDTC/DSSTDTC

SUPPDS.QVAL, when QNAM=ICFVRDTC

SUPPDS.QVAL, when QNAM=ICFVRN

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the most current IRB approved version of the Informed Consent signed by the subject?	DSYN	Categorical yes/no (dichotomous)	3	
[2]	Date Subject Signed ICF: (Original signature)	DSDAT	Date	11	
[3]	ICF Version:	DSVERS	Categorical select one (nominal)	17	v1 ICF CEG-P1-078 v2 ICF CEG-P1-078
[4]	ICF Version Date:	DSVDAT	Date	11	

[NOT SUBMITTED]

CEG_P1_078

Visit Date at Screening,Day -1,Day 1,Day 2,Day 3,Day 4,Day 5,Day 6,Early Term

Visit Done? ○ Yes ○ No **[1]**

Date of Visit: _____ **[2]**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit Done?	SVYN	Categorical yes/no (dichotomous)	3	
[2]	Date of Visit:	SVSTDAT	Date	11	

IE=Inclusion/ Exclusion Criteria Not Met

CO=COMMENTS

CEG_P1_078

INCL/EXCL Criteria Summary at Screening

Does the subject meet all eligibility criteria required by the protocol? ○ Yes ○ No

[NOT SUBMITTED]

IECAT=INCLUSION

If NO, please specify the inclusion and/or exclusion criteria number:

	Specify: [2]	Number: [3]	Comment: [4]
1	○ Inclusion criteria ○ Exclusion criteria		

More rows: 1 5 10

COVAL where COREF=INCLUSION/ EXCLUSION CRITERIA

IECAT=EXCLUSION

IETESTCD=EXCLXX when IECAT=EXCLUSION or INCLXX when IECAT=INCLUSION

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Does the subject meet all eligibility criteria required by the protocol?	IEYN	Categorical yes/no (dichotomous)	3	
[2]	Specify:	IECAT	Categorical select one (nominal)	18	
[3]	Number:	IETESTCD	Categorical select one (nominal)	6	INCL01 INCL02 INCL03 INCL04 INCL05 INCL06 INCL07 INCL08 INCL09 INCL10 INCL11 EXCL01 EXCL02 EXCL03 EXCL04 EXCL05 EXCL06 EXCL07 EXCL08 EXCL09 EXCL10 EXCL11 EXCL12 EXCL13 EXCL14 EXCL15 EXCL16 EXCL17 EXCL18
[4]	Comment:	IECOM	Text or Any Value	200	

DM=Demographics

CEG_P1_078

Demographics at Screening

Visit Date: [1] DMDTC

Date of Birth: [2] BRTHDTC

Age: [3] AGE

Age Unit: [4] AGEU

Gender: [5] SEX
- M
- F

Ethnicity: [6] ETHNIC
- HISPANIC OR LATINO
- NOT HISPANIC OR LATINO
- UNKNOWN

Race: [7] RACE
- WHITE
- BLACK OR AFRICAN AMERICAN
- ASIAN
- AMERICAN INDIAN OR ALASKA NATIVE
- NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
- OTHER

Set to MULTIPLE and individual race values are captured as SUPPDM.QVAL where QNAM=RACE1, RACE2, etc. when more than one race selected

Other, Specify: [8] SUPPDM.QVAL where QNAM=RACEOTH

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit Date:	DMDAT	Date	11	
[2]	Date of Birth:	DMBRTHDAT	Date	11	
[3]	Age:	DMAGE	Number (continuous)	15	
[4]	Age Unit:	DMAGEU	Text or Any Value	4000	
[5]	Gender:	DMSEX	Categorical select one (nominal)	1	
[6]	Ethnicity:	DMETHNIC	Categorical select one (nominal)	22	
[7]	Race:	DMRACE	Categorical select multiple	41	
[8]	Other, Specify:	DMRCOT	Text or Any Value	200	

MH=Medical History

CEG_P1_078

Medical History at Screening **MHCAT=GENERAL**

Does the subject have any relevant medical or surgical history (including drug allergies)? ○ Yes ○ No **[NOT SUBMITTED]**

Date of Visit: _____ **MHDTC**

MHTERM

MHENRF

	Medical History #: [3]	Body System Code: [4]	If other, please specify: [5]	Condition: [6]	Onset Date: [7]	Date Resolved: [8]	Ongoing? [9]	Safety Review: [10]	
1							○ Yes ○ No	○ Not Clinically Sigficant	○ Clinically Significant
	MHSPID	**MHSCAT**	**SUPPMH.QVAL where QNAM=MHOTHSP**		**MHSTDTC**	**MHENDTC**			**SUPPMH.QVAL where QNAM=MHCLSIG**

More rows: 1 5 10

Does the subject self-report the desire to smoke within approximately 30 minutes of waking? **[11]** **SUPPMH.QVAL where QNAM=MHSMK**

Does the subject have a history of recreational drug use? **[12]** **SUPPMH.QVAL where QNAM=MHRECUSE**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Does the subject have any relevant medical or surgical history (including drug allergies)?	MHYN	Categorical yes/no (dichotomous)	3	
[2]	Date of Visit:	MHDAT	Date	11	
[3]	Medical History #:	MHNUM	Number (continuous)	15	
[4]	Body System Code:	MHSCAT	Categorical select one (nominal)	34	HEENT Respiratory Cardiovascular Gastrointestinal Genitourinary/Renal Musculoskeletal Psychiatric/Neurologic Endocrine/Metabolic Hematopoietic/Lymphatic Dermatologic Immunologic/Allergies Oncologic Acute, Chronic, Infectious Disease Hepatic Surgical Other, Specify
[5]	If other, please specify:	MHOTHSP	Text or Any Value	200	
[6]	Condition:	MHSCAT	Text or Any Value	200	
[7]	Onset Date:	MHSTDAT	Date	11	
[8]	Date Resolved:	MHENDAT	Date	11	
[9]	Ongoing?	MHONGO	Categorical yes/no (dichotomous)	3	
[10]	Safety Review:	MHCLSIG	Categorical select one (nominal)	24	
[11]	Does the subject self-report the desire to smoke within approximately 30 minutes of waking?	MHSMK	Categorical yes/no (dichotomous)	3	Yes No
[12]	Does the subject have a history of recreational drug use?	MHRECUSE	Categorical yes/no (dichotomous)	3	Yes No

RP=Reproductive System Findings

CEG_P1_078

Female Contraceptive Method at Screening

RPCAT=FEMALE CONTRACEPTIVE METHOD

Visit Date [1] **RPDTC**

Childbearing Potential:
- CHILDBEARING POTENTIAL [2]
- NON-CHILDBEARING POTENTIAL

RPTEST=Childbearing Potential
RPTESTCD=CHILDPOT
RPORRES should be "Yes" if Childbearing Potential and "No" if Non-Childbearing Potential

Is subject considered post-menopausal?
- Yes [3]
- No

RPORRES when RPTESTCD=MENOSTAT

Last menses: [4] **RPORRES when RPTESTCD=LMPSTDTC**

Please select the contraceptive method used by subject: [5] Start Date: [6]

SUPPRP.QVAL where QNAM=BCMSTDTC

1

RPTESTCD=BCMETHOD

More rows: 1 5 10

Females of non-childbearing potential must meet at least one of the following criteria: [7] Procedure Date: [8]

1

if one criteria meet then SUPPRP.QVAL where QNAM=SCSUR else QNAM=SCSUR1 & etc.

SUPPRP.QVAL where QNAM=SCPRODAT

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit Date	SCDAT	Date	11	
[2]	Childbearing Potential:	SCSTATUS	Categorical select one (nominal)	26	
[3]	Is subject considered post-menopausal?	SCPOST	Categorical yes/no (dichotomous)	3	
[4]	Last menses:	SCMENDAT	Date	11	
[5]	Please select the contraceptive method used by subject:	SCTEST	Categorical select one (nominal)	32	ABSTINENCE BIRTH CONTROL PILL CONDOM WITH SPERMICIDE CONDOM WITH DIAPHRAGM CONDOM WITH CONTRACEPTIVE SPONGE INTRAUTERINE DEVICE
[6]	Start Date:	SCSTDAT	Date	11	
[7]	Females of non-childbearing potential must meet at least one of the following criteria:	SCSUR	Categorical select one (nominal)	57	Bilateral salpingo-oopherectomy or bilateral oopherectomy Tubal Ligation Hysterectomy Hysterectomy with bilateral salpingo-oopherectomy Post-menopausal
[8]	Procedure Date:	SCPRODAT	Date	11	

PE=Physical Examination

CEG_P1_078

Complete Physical Examination at Screening

PECAT=COMPLETE

Was the physical examination performed? ○Yes ○No **[1]**

PESTAT=NOT DONE where PETESTCD=PEALL

Examination Date: **[2]**

PEDTC

Completion Time: **[3]**

Timepart of PEDTC

PETEST

	Body System Examined: **[4]**	Not done: **[5]**	If Other, please specify: **[6]**	Examination Result: **[7]**	Abnormal Findings: **[8]**
1	GENERAL APPEARANCE	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	
2	HEENT	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	
3	NECK/THYROID	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	
4	CARDIOVASCULAR	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	
5	RESPIRATORY	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	
6	GASTROINTESTINAL	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	
7	NEUROLOGICAL	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	
8	MUSCULOSKELETAL/EXTREMITIES	☐		○NORMAL ○ABNORMAL NCS ○ABNORMAL CS	

PESTAT

PEORRES

PEORRES is "NORMAL" or concatenation of "ABNORMAL" and abnormal findings value in parenthesis

SUPPPE.QVAL="NCS" where QNAM=PECLSIG if the examination result is "ABNORMAL NCS" or SUPPPE.QVAL="CS" where QNAM=PECLSIG if the examination result is "ABNORMAL CS"

For Annotations see Page 17

CEG_P1_078

9	SKIN	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
10	OTHER	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	

SUPPPE.QVAL where QNAM=PETESTOT

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the physical examination performed?	PEYN	Categorical yes/no (dichotomous)	3	
[2]	Examination Date:	PEDAT	Date	11	
[3]	Completion Time:	PETIM	Time	5	
[4]	Body System Examined:	PETEST	Categorical select one (nominal)	27	GENERAL APPEARANCE HEENT NECK/THYROID CARDIOVASCULAR RESPIRATORY GASTROINTESTINAL NEUROLOGICAL SKIN OTHER MUSCULOSKELETAL/EXTREMITIES
[5]	Not done:	PESTAT	Categorical yes/no (dichotomous)	3	
[6]	If Other, please specify:	PEOTHSP	Text or Any Value	200	
[7]	Examination Result:	PEORRES	Categorical select one (nominal)	12	
[8]	Abnormal Findings:	PEDESC	Text or Any Value	200	

For Annotations see Page 17

CEG_P1_078

Complete Physical Examination at Unscheduled Visit

Visit: [ ] **[1]** *[NOT SUBMITTED]*

Was the physical examination performed? ○ Yes ○ No **[2]**

Examination Date: [ ] **[3]**

Completion Time: [ ] **[4]**

For Annotations see Page 17

CEG_P1_078

	Body System Examined: [5]	Not done: [6]	If Other, please specify: [7]	Examination Result: [8]	Abnormal Findings: [9]
1	GENERAL APPEARANCE	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
2	HEENT	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
3	NECK/THYROID	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
4	CARDIOVASCULAR	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
5	RESPIRATORY	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
6	GASTROINTESTINAL	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
7	NEUROLOGICAL	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
8	MUSCULOSKELETAL/EXTREMITIES	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
9	SKIN	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	
10	OTHER	☐		○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	

SUPPPE.QVAL where QNAM=PETESTOT

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	PEVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the physical examination performed?	PEYN	Categorical yes/no (dichotomous)	3	
[3]	Examination Date:	PEDAT	Date	11	
[4]	Completion Time:	PETIM	Time	5	
[5]	Body System Examined:	PETEST	Categorical select one (nominal)	27	GENERAL APPEARANCE HEENT NECK/THYROID CARDIOVASCULAR RESPIRATORY GASTROINTESTINAL NEUROLOGICAL SKIN OTHER MUSCULOSKELETAL/EXTREMITIES
[6]	Not done:	PESTAT	Categorical yes/no (dichotomous)	3	
[7]	If Other, please specify:	PEOTHSP	Text or Any Value	200	
[8]	Examination Result:	PEORRES	Categorical select one (nominal)	12	
[9]	Abnormal Findings:	PEDESC	Text or Any Value	200	

For Annotations see Page 17, 18

CEG_P1_078

Symptom Directed Physical Exam at Day -1,Day 6

PECAT=SYMPTOM DIRECTED

Was physical examination performed? ○ Yes ○ No **[1]**

Examination Date: _____ **[2]**

Completion Time: _____ **[3]**

ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM

	Body System Examined: **[4]**	Not done: **[5]**	If Other, please specify: **[6]**	Examination Results: **[7]**	Abnormal Findings: **[8]**
1	General Appearance	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
2	Respiratory	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
3	Cardiovascular	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
4	Gastrointestinal	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
5	Other	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was physical examination performed?	PEYN	Categorical yes/no (dichotomous)	3	
[2]	Examination Date:	PEDAT	Date	11	
[3]	Completion Time:	PTIM	Time	5	
[4]	Body System Examined:	PETEST	Categorical select one (nominal)	18	General Appearance Respiratory Cardiovascular Gastrointestinal Other
[5]	Not done:	PESTAT	Categorical yes/no (dichotomous)	3	
[6]	If Other, please specify:	PEOTHSP	Text or Any Value	200	
[7]	Examination Results:	PEORRES	Categorical select one (nominal)	12	
[8]	Abnormal Findings:	PECLSIG	Text or Any Value	200	

For Annotations see Page 17, 18

CEG_P1_078

Symptom Directed Physical Exam at Early Term,Unscheduled Visit *PECAT=SYMPTOM DIRECTED*

Visit: [ ] **[1]** *[NOT SUBMITTED]*

Was physical examination performed? ○ Yes ○ No **[2]**

Examination Date: [ ] **[3]**

Completion Time: [ ] **[4]**

ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM

	Body System Examined: **[5]**	Not done: **[6]**	If Other, please specify: **[7]**	Examination Results: **[8]**	Abnormal Findings: **[9]**
1	General Appearance	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
2	Respiratory	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
3	Cardiovascular	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
4	Gastrointestinal	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	
5	Other	☐		○ Normal ○ Abnormal NCS ○ Abnormal CS	

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	PEVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination NA
[2]	Was physical examination performed?	PEYN	Categorical yes/no (dichotomous)	3	
[3]	Examination Date:	PEDAT	Date	11	
[4]	Completion Time:	PTIM	Time	5	
[5]	Body System Examined:	PETEST	Categorical select one (nominal)	18	General Appearance Respiratory Cardiovascular Gastrointestinal Other
[6]	Not done:	PESTAT	Categorical yes/no (dichotomous)	3	
[7]	If Other, please specify:	PEOTHSP	Text or Any Value	200	
[8]	Examination Results:	PEORRES	Categorical select one (nominal)	12	
[9]	Abnormal Findings:	PECLSIG	Text or Any Value	200	

VS=Vital Signs

CEG_P1_078

Height, Weight and BMI at Screening

Was the assessment performed? ○ Yes ○ No

VSSTAT=NOT DONE where VSTESTCD=VSALL

Visit Date: _____ **VSDTC** **[2]**

Height: _____ cm **[3]** **VSORRES/VSORRESU when VSTESTCD=HEIGHT**

Weight: _____ kg **[4]** **VSORRES/VSORRESU when VSTESTCD=WEIGHT**

BMI: _____ kg/m² **[5]** **VSORRES/VSORRESU when VSTESTCD=BMI**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the assessment performed?	VSYN	Categorical yes/no (dichotomous)	3	
[2]	Visit Date:	VSDAT	Date	11	
[3]	Height:	VSHGT	Number (continuous)	15	
[4]	Weight:	VSWGT	Number (continuous)	15	
[5]	BMI:	VSBMI	Number (continuous)	15	

LB=Laboratory Test Results

CEG_P1_078

Serology Lab Evaluation at Screening

LBCAT=SEROLOGY

Was the laboratory evaluation performed? ○ Yes [1] ○ No

LBSTAT=NOT DONE, where LBTESTCD=LBALL

LBDTC

Date of collection: [2] Time of Collection: [3] Time Unknown: [4]

NOT SUBMITTED

Are all results within normal limits? ○ Yes [5] ○ No

LBNRIND

LBTEST

	Test Name: [6]	Clinical Significance as per MD: **(Please record an AE for Clinically Significant results) [7]**
1		○ NCS ○ CS

SUPPLB.QVAL, when SUPPLB.QNAM=LBCLSIG

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[5]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[6]	Test Name:	LBTEST	Categorical select one (nominal)	37	HUMAN IMMUNODEFICIENCY VIRUS ANTIBODY HEPATITIS B VIRUS SURFACE ANTIGEN HEPATITIS C VIRUS ANTIBODY
[7]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

For Annotations see Page 29

CEG_P1_078

Serology Lab Evaluation at Unscheduled Visit

Visit: [1] [NOT SUBMITTED]

Was the laboratory evaluation performed? Yes [2] No

Date of collection: [3] Time of Collection: [4] Time Unknown: [5]

Are all results within normal limits? Yes [6] No

	Test Name: [7]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [8]
1		NCS CS

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[6]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[7]	Test Name:	LBTEST	Categorical select one (nominal)	37	HUMAN IMMUNODEFICIENCY VIRUS ANTIBODY HEPATITIS B VIRUS SURFACE ANTIGEN HEPATITIS C VIRUS ANTIBODY
[8]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

LB=Laboratory Test Results

CEG_P1_078

Serum Pregnancy Test at Screening LBCAT=PREGNANCY LBTESTCD=HCG LBSPEC=SERUM

Was Serum Pregnancy Test performed? ○ Yes [1] ○ No

LBSTAT=NOT DONE, where LBTESTCD=LBALL

LBDTC

Date of collection: [2] Time of Collection: [3] Time Unknown: [4]

[NOT SUBMITTED]

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Serum Pregnancy Test performed?	LBHCGYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	

For Annotations see Page 33

CEG_P1_078

Serum Pregnancy Test at Unscheduled Visit

Visit: [NOT SUBMITTED]

Was Serum Pregnancy Test performed? ○ Yes **[2]** ○ No

Date of collection: **[3]** Time of Collection: **[4]** Time Unknown: **[5]**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was Serum Pregnancy Test performed?	LBHCGYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	

LB=Laboratory Test Results

CEG_P1_078

Urine Pregnancy Test at Day -1 LBCAT=PREGNANCY LBTESTCD=HCG LBSPEC=URINE

Was Urine Pregnancy Test performed? ○ Yes [1] ○ No LBSTAT=NOT DONE, where LBTESTCD=LBALL

Date of collection: [2] Time of Collection: [3] Time Unknown: ☐ [4] NOT SUBMITTED

LBDTC

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Urine Pregnancy Test performed?	LBHCGYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	

For Annotations see Page 37

CEG_P1_078

Urine Pregnancy Test at Unscheduled Visit

Visit: [1]

Was Urine Pregnancy Test performed? Yes [2] No

Date of collection: [3] Time of Collection: [4] Time Unknown: [5]

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was Urine Pregnancy Test performed?	LBHCGYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	

LB=Laboratory Test Results

CEG_P1_078

UDS and Alcohol Laboratory Evaluation at Screening,Day -1

LBCAT=URINE DRUG SCREEN

Was the laboratory evaluation performed? ○ Yes **[1]** ○ No

LBSTAT=NOT DONE, where LBTESTCD=LBALL

LBDTC

Date of collection: **[2]** Time of Collection: **[3]** Time Unknown: **[4]**

[NOT SUBMITTED]

Are all results within normal limits? ○ Yes **[5]** ○ No

LBNRIND

LBTEST

	Test Name: **[6]**	Clinical Significance as per MD: **[7]**	
1		○ NCS ○ CS	

SUPPLB.QVAL, when SUPPLB.QNAM=LBCLSIG

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[5]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[6]	Test Name:	LBTEST	Categorical select one (nominal)	26	Tetrahydrocannabinol (THC) Opioids Amphetamines Cocaine Benzodiazepines Alcohol Morphine Codeine Heroin Hydrocodone Hydromorphone Oxycodone
[7]	Clinical Significance as per MD:	LBCLSIG	Categorical select one (nominal)	3	

For Annotations see Page 41

CEG_P1_078

UDS and Alcohol Laboratory Evaluation at Unscheduled Visit

Visit: [NOT SUBMITTED]

Was the laboratory evaluation performed? ○ Yes **[2]** ○ No

Date of collection: **[3]** Time of Collection: **[4]** Time Unknown: ☐ **[5]**

Are all results within normal limits? ○ Yes **[6]** ○ No

	Test Name: **[7]**	Clinical Significance as per MD: **[8]**
1		○ NCS ○ CS

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[6]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[7]	Test Name:	LBTEST	Categorical select one (nominal)	26	Tetrahydrocannabinol (THC) Opioids Amphetamines Cocaine Benzodiazepines Alcohol Morphine Codeine Heroin Hydrocodone Hydromorphone Oxycodone
[8]	Clinical Significance as per MD:	LBCLSIG	Categorical select one (nominal)	3	

LB=Laboratory Test Results

CEG_P1_078

Cotinine Evaluation at Screening **LBCAT=COTININE**

Was the laboratory evaluation performed? ○ Yes ○ No **[1]** **LBSTAT=NOT DONE, where LBTESTCD=LBALL**

Date of collection: **[2]** Time of Collection: **[3]** Time Unknown: ☐ **[4]** **[NOT SUBMITTED]**

LBDTC

Is the result within range? ○ Yes **[5]** **LBNRIND**

○ No

LBTEST

Test Name: **[6]** Clinical Significance as per MD: **[7]**

1 Cotinine ○ NCS ○ CS **SUPPLB.QVAL, when SUPPLB.QNAM=LBCLSIG**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[5]	Is the result within range?	LBNRIND	Categorical yes/no (dichotomous)	3	
[6]	Test Name:	LBTEST	Categorical select one (nominal)	8	Cotinine
[7]	Clinical Significance as per MD:	LBCLSIG	Categorical select one (nominal)	3	

For Annotations see Page 45

CEG_P1_078

Cotinine Evaluation at Unscheduled Visit

Visit: [1] [NOT SUBMITTED]

Was the laboratory evaluation performed? ○ Yes ○ No [2]

Date of collection: [3] Time of Collection: [4] Time Unknown: [5]

Is the result within range? ○ Yes [6] ○ No

Test Name: [7] Clinical Significance as per MD: [8]

1 Cotinine ○ NCS ○ CS

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[6]	Is the result within range?	LBNRIND	Categorical yes/no (dichotomous)	3	
[7]	Test Name:	LBTEST	Categorical select one (nominal)	8	Cotinine
[8]	Clinical Significance as per MD:	LBCLSIG	Categorical select one (nominal)	3	

LB=Laboratory Test Results

CEG_P1_078

Chemistry Laboratory Evaluation at Screening,Day 6 **LBCAT=CHEMISTRY**

Was the laboratory evaluation performed? ○ Yes **[1]** **LBSTAT=NOT DONE, where LBTESTCD=LBALL**
○ No

LBDTC

Date of collection: **[2]** Time of Collection: **[3]** Time Unknown: ☐ **[4]** **[NOT SUBMITTED]**

Are all results within normal limits? ○ Yes **[5]** **LBNRIND**
○ No

LBTEST

Test Name: **[6]** Clinical Significance as per MD: **(Please record an AE for Clinically Significant results) [7]**

1 ○ NCS ○ CS **SUPPLB.QVAL, when SUPPLB.QNAM=LBCLSIG**

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[5]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[6]	Test Name:	LBTEST	Categorical select one (nominal)	32	Sodium Potassium Glucose Creatinine Total Protein Blood Urea Nitrogen (BUN) Albumin Total Bilirubin Alanine Transferase (ALT) Aspartate Transferase (AST) Lactate Dehydrogenase (LD) Gamma-Glutamyl Transferase (GGT) Alkaline Phosphatase Creatine Phosphokinase (CK)
[7]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

For Annotations see Page 49

CEG_P1_078

Chemistry Laboratory Evaluation at Early Term,Unscheduled Visit

Visit: [1] *[NOT SUBMITTED]*

Was the laboratory evaluation performed? Yes **[2]** No

Date of collection: **[3]** Time of Collection: **[4]** Time Unknown: **[5]**

Are all results within normal limits? Yes **[6]** No

Test Name: **[7]** Clinical Significance as per MD: **(Please record an AE for Clinically Significant results) [8]**

1 NCS CS

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[6]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[7]	Test Name:	LBTEST	Categorical select one (nominal)	32	Sodium Potassium Glucose Creatinine Total Protein Blood Urea Nitrogen (BUN) Albumin Total Bilirubin Alanine Transferase (ALT) Aspartate Transferase (AST) Lactate Dehydrogenase (LD) Gamma-Glutamyl Transferase (GGT) Alkaline Phosphatase Creatine Phosphokinase (CK)
[8]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

LB=Laboratory Test Results

CEG_P1_078

Hematology Laboratory Evaluation at Screening,Day 6

LBCAT=HEMATOLOGY

Was the laboratory evaluation performed? ○ Yes **[1]** ○ No

LBSTAT=NOT DONE, where LBTESTCD=LBALL

Date of collection: **[2]** Time of Collection: **[3]** Time Unknown **[4]**

[NOT SUBMITTED]

LBDTC

LBTEST

Are all results within normal limits? ○ Yes **[5]** ○ No

LBNRIND

	Test Name: **[6]**	Clinical Significance as per MD: **(Please record an AE for Clinically Significant results) [7]**
1		○ NCS ○ CS

SUPPLB.QVAL, when SUPPLB.QNAM=LBCLSIG

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[5]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[6]	Test Name:	LBTEST	Categorical select one (nominal)	20	HEMATOCRIT HEMOGLOBIN RED BLOOD CELL WHITE BLOOD CELL PLATELET COUNT NEUTROPHILS ABSOLUTE NEUTROPHILS LYMPHOCYTES ABSOLUTE LYMPHOCYTES MONOCYTES ABSOLUTE MONOCYTES EOSINOPHILS ABSOLUTE EOSINOPHILS BASOPHILS ABSOLUTE BASOPHILS
[7]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

For Annotations see Page 53

CEG_P1_078

Hematology Laboratory Evaluation at Early Term,Unscheduled Visit

Visit: [1] [NOT SUBMITTED]

Was the laboratory evaluation performed? Yes [2] No

Date of collection: [3] Time of Collection: [4] Time Unknown: [5]

Are all results within normal limits? Yes [6] No

Test Name: [7] Clinical Significance as per MD: **(Please record an AE for Clinically Significant results)** [8]

1 NCS CS

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[6]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[7]	Test Name:	LBTEST	Categorical select one (nominal)	20	HEMATOCRIT HEMOGLOBIN RED BLOOD CELL WHITE BLOOD CELL PLATELET COUNT NEUTROPHILS ABSOLUTE NEUTROPHILS LYMPHOCYTES ABSOLUTE LYMPHOCYTES MONOCYTES ABSOLUTE MONOCYTES EOSINOPHILS ABSOLUTE EOSINOPHILS BASOPHILS ABSOLUTE BASOPHILS
[8]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

LB=Laboratory Test Results

CEG_P1_078

Urinalysis Laboratory Evaluation at Screening,Day 6

LBCAT=URINALYSIS

Was the laboratory evaluation performed? ○ Yes **[1]** ○ No

LBSTAT=NOT DONE, where LBTESTCD=LBALL

Date of collection: **[2]** Time of Collection: **[3]** Time Unknown: ☐ **[4]**

[NOT SUBMITTED]

LBDTC

Are all results within normal limits? ○ Yes **[5]** ○ No

LBNRIND

LBTEST

	Test Name: **[6]**	Clinical Significance as per MD: **(Please record an AE for Clinically Significant results) [7]**	
1		○ NCS ○ CS	**SUPPLB.QVAL, when SUPPLB.QNAM=LBCLSIG**

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[5]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[6]	Test Name:	LBTEST	Categorical select one (nominal)	25	Color Nitrite Specific Gravity pH Protein Glucose Ketones Occult Blood Bilirubin Urobilinogen WBC RBC Squamous Epithelial Cells Bacteria Hyaline Cast Crystals
[7]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

For Annotations see Page 57

CEG_P1_078

Urinalysis Laboratory Evaluation at Early Term,Unscheduled Visit

Visit: [1] [NOT SUBMITTED]

Was the laboratory evaluation performed? Yes [2] / No

Date of collection: [3] Time of Collection: [4] Time Unknown: [5]

Are all results within normal limits? Yes [6] / No

	Test Name: [7]	Clinical Significance as per MD: **(Please record an AE for Clinically Significant results)** [8]
1		NCS CS

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[6]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[7]	Test Name:	LBTEST	Categorical select one (nominal)	25	Color Nitrite Specific Gravity pH Protein Glucose Ketones Occult Blood Bilirubin Urobilinogen WBC RBC Squamous Epithelial Cells Bacteria Hyaline Cast Crystals
[8]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

LB=Laboratory Test Results

CEG_P1_078

Endocrinology Evaluation at Screening LBCAT=ENDOCRINOLOGY

Was the laboratory evaluation performed? ○ Yes [1] ○ No

LBSTAT=NOT DONE, where LBTESTCD=LBALL

Date of collection: [2] Time of Collection: [3] Time Unknown: ☐ [4]

LBDTC

[NOT SUBMITTED]

Are all results within normal limits? ○ Yes [5] ○ No

LBNRIND

LBTEST

Test Name: [6]

Clinical Significance as per MD:
(Please record an AE for Clinically Significant results) [7]

1 FSH (Follicle-Stimulating Hormone) ○ NCS ○ CS

SUPPLB.QVAL, when SUPPLB.QNAM=LBCLSIG

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[2]	Date of collection:	LBDAT	Date	11	
[3]	Time of Collection:	LBTIM	Time	5	
[4]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[5]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[6]	Test Name:	LBTEST	Categorical select one (nominal)	34	FSH (Follicle-Stimulating Hormone)
[7]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

For Annotations see Page 61

CEG_P1_078

Endocrinology Evaluation at Unscheduled Visit

Visit: [1]

Was the laboratory evaluation performed? ○ Yes [2] ○ No [NOT SUBMITTED]

Date of collection: [3] Time of Collection: [4] Time Unknown: [5]

Are all results within normal limits? ○ Yes [6] ○ No

	Test Name: [7]	Clinical Significance as per MD: **(Please record an AE for Clinically Significant results)** [8]
1	FSH (Follicle-Stimulating Hormone)	○ NCS ○ CS

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	LBVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Was the laboratory evaluation performed?	LBYN	Categorical yes/no (dichotomous)	3	
[3]	Date of collection:	LBDAT	Date	11	
[4]	Time of Collection:	LBTIM	Time	5	
[5]	Time Unknown:	LBTMNK	Categorical yes/no (dichotomous)	3	
[6]	Are all results within normal limits?	LBNRIND	Categorical yes/no (dichotomous)	3	
[7]	Test Name:	LBTEST	Categorical select one (nominal)	34	FSH (Follicle-Stimulating Hormone)
[8]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

VS=Vital Signs

CEG_P1_078

Vital Signs at Screening,Day -1,Day 6

Were vital signs measured? ○ Yes [1] ○ No

VSSTAT=NOT DONE where VSTESTCD=VSALL

Repeat vital signs? ○ Yes [○ No

[NOT SUBMITTED]

QVAL where SUPPVS. QNAM=TIMESPOS

Time Seated: [3] Time Seated Unknown: ☐ [4]

[NOT SUBMITTED]

VSDTC

Date: [5] Time Taken: [6] Time Unknown: ☐ [7]

	VSTEST Assessment: [8]	**VSSTAT** Not done: [9]	**VSORRES** Result: [10]	**VSORRESU** Unit: [11]	MD Safety Review: [12]
1	Oral Temperature	☐		C	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
2	Systolic Blood Pressure	☐		mmHg	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
3	Diastolic Blood Pressure	☐		mmHg	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
4	Pulse Rate	☐		beats/min	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
5	Respirations	☐		breaths/min	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS

QVAL where SUPPVS. QNAM=VSCLSIG

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Were vital signs measured?	VSPERF	Categorical yes/no (dichotomous)	3	
[2]	Repeat vital signs?	VSPERFR	Categorical yes/no (dichotomous)	3	
[3]	Time Seated:	VS1TIMS	Time	5	
[4]	Time Seated Unknown:	VSTIMSUN	Categorical yes/no (dichotomous)	3	
[5]	Date:	VSDAT	Date	11	
[6]	Time Taken:	VSTIM	Time	5	
[7]	Time Unknown:	VSTMNK	Categorical yes/no (dichotomous)	3	
[8]	Assessment:	VSTEST	Categorical select one (nominal)	24	Oral Temperature Systolic Blood Pressure Diastolic Blood Pressure Pulse Rate Respirations Heart Rate
[9]	Not done:	VSSTAT	Categorical yes/no (dichotomous)	3	
[10]	Result:	VSORRES	Number (continuous)	15	
[11]	Unit:	VSORRESU	Categorical select one (nominal)	11	C mmHg beats/min breaths/min
[12]	MD Safety Review:	VSCLSIG	Categorical select one (nominal)	26	

For Annotations see Page 65

CEG_P1_078

Vital Signs at Early Term

Visit: [NOT SUBMITTED]

Were vital signs measured? ○ Yes **[2]** ○ No

Repeat vital signs? ○ Yes **[3]** ○ No

Time Seated: **[4]** Time Seated Unknown: ☐ **[5]**

Date: **[6]** Time Taken: **[7]** Time Unknown: ☐ **[8]**

	Assessment: **[9]**	Not done: **[10]**	Result: **[11]**	Unit: **[12]**	MD Safety Review: **[13]**
1	Oral Temperature	☐		C	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
2	Systolic Blood Pressure	☐		mmHg	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
3	Diastolic Blood Pressure	☐		mmHg	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
4	Pulse Rate	☐		beats/min	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
5	Respirations	☐		breaths/min	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	VSVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Were vital signs measured?	VSPERF	Categorical yes/no (dichotomous)	3	
[3]	Repeat vital signs?	VSPERFR	Categorical yes/no (dichotomous)	3	
[4]	Time Seated:	VS1TIMS	Time	5	
[5]	Time Seated Unknown:	VSTIMSUN	Categorical yes/no (dichotomous)	3	
[6]	Date:	VSDAT	Date	11	
[7]	Time Taken:	VSTIM	Time	5	
[8]	Time Unknown:	VSTMNK	Categorical yes/no (dichotomous)	3	
[9]	Assessment:	VSTEST	Categorical select one (nominal)	24	Oral Temperature Systolic Blood Pressure Diastolic Blood Pressure Pulse Rate Respirations Heart Rate
[10]	Not done:	VSSTAT	Categorical yes/no (dichotomous)	3	
[11]	Result:	VSORRES	Number (continuous)	15	
[12]	Unit:	VSORRESU	Categorical select one (nominal)	11	C mmHg beats/min breaths/min
[13]	MD Safety Review:	VSCLSIG	Categorical select one (nominal)	26	

DA=Drug Accountability

CEG_P1_078

Part A - Usual Brand Dose Log at Day 1,Day 2,Day 3

DASCAT=USUAL BRAND CIGARETTES

DAGRPID=PART A

DACAT=STUDY PRODUCT

AD LIB USUAL BRAND (MENTHOL) PRODUCT USE LOG

Date part of DADTC

Date of Visit: [1]

	Product Used: [2]	Number Dispensed: [3]	Time Dispensed: [4]	Number of Butts Returned: [5]	Time Returned: [6]
1					

More rows: 1 5 10

Time part of DADTC when DATESTCD=DISPAMT

Time part of DADTC when DATESTCD=RETAMT

DAORRES when DATESTCD=DISPAMT

DAORRES when DATESTCD=RETAMT

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXDAT	Date	11	
[2]	Product Used:	EXPRDT	Categorical select one (nominal)	21	Combustible Cigarette
[3]	Number Dispensed:	EXDSPD	Number (continuous)	15	
[4]	Time Dispensed:	EXTIM	Time	5	
[5]	Number of Butts Returned:	EXCIGRET	Number (continuous)	15	
[6]	Time Returned:	EXTIMRET	Time	5	

For Annotations see Page 69

CEG_P1_078

Part A - VLN Dosing Log at Day 1,Day 2,Day 3

AD LIB VERY LOW NICOTINE (VLN) (MENTHOL) PRODUCT USE LOG

Date of Visit: [ ] **[1]**

	Product Used: **[2]**	Number Dispensed: **[3]**	Time Dispensed: **[4]**	Number of Butts Returned: **[5]**	Time Returned: **[6]**
1					

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXDAT	Date	11	
[2]	Product Used:	EXPRDT	Categorical select one (nominal)	21	Combustible Cigarette
[3]	Number Dispensed:	EXDSPD	Number (continuous)	15	
[4]	Time Dispensed:	EXTIM	Time	5	
[5]	Number of Butts Returned:	EXCIGRET	Number (continuous)	15	
[6]	Time Returned:	EXTIMRET	Time	5	

For Annotations see Page 69

CEG_P1_078

Part A - Nicorette Dosing Log at Day 1,Day 2,Day 3

AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG

Date of Visit: [ ] **[1]**

	Product Used: **[2]**	Number Dispensed: **[3]**	Time Dispensed: **[4]**	Number of Pieces Returned: **[5]**	Time Returned/Discarded: **[6]**
1					

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXDAT	Date	11	
[2]	Product Used:	EXPRDT	Categorical select one (nominal)	36	Nicorette Original Flavor Gum (4 mg)
[3]	Number Dispensed:	EXDSPD	Number (continuous)	15	
[4]	Time Dispensed:	EXTIM	Time	5	
[5]	Number of Pieces Returned:	EXNICRET	Number (continuous)	15	
[6]	Time Returned/Discarded:	EXTIMRET	Time	5	

EX=Exposure

CEG_P1_078

EXGRPID=PART B

EXROUTE=ORAL

EXLOC=ORAL CAVITY

Part B - Controlled Nicorette Dosing Log at Day 4,Day 5,Day 6

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG

(Subject to use one unit of product ad libitum for 10 minutes)

Date of Visit: [ ] **[1]**

Date part of EXSTDTC/EXENDTC

EXTRT

	Product: **[2]**	Session Start Time: **[3]**	Session End Time: **[4]**
1	[ ]	[ ]	[ ]

Time part of EXENDTC

More rows: 1 5 10

Time part of EXSTDTC

Did the subject consume any beverages during controlled product use?: ○ Yes ○ No **[5]**

SUPPEX.QVAL, when QNAM is EXBEV

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXNICDAT	Date	11	
[2]	Product:	EXPRDB	Categorical select one (nominal)	36	Nicorette Original Flavor Gum (4 mg)
[3]	Session Start Time:	EXSRTTIMB	Time	5	
[4]	Session End Time:	EXENTMB	Time	5	
[5]	Did the subject consume any beverages during controlled product use?:	EXBEV	Categorical yes/no (dichotomous)	3	

For Annotations see Page 75

CEG_P1_078

Part B - Uncontrolled Nicorette Dosing Log at Day 4,Day 5,Day 6

UNCONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG

(Subject to use one unit of product ad libitum for 10 minutes)

Date of Visit: [ ] **[1]**

	Product: **[2]**	Session Start Time: **[3]**	Session End Time: **[4]**
1	[ ]	[ ]	[ ]

More rows: 1 5 10

Did the subject consume any beverages during controlled product use?: ○ Yes ○ No **[5]**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXNICDAT	Date	11	
[2]	Product:	EXPRDB	Categorical select one (nominal)	36	Nicorette Original Flavor Gum (4 mg)
[3]	Session Start Time:	EXSRTTIMB	Time	5	
[4]	Session End Time:	EXENTMB	Time	5	
[5]	Did the subject consume any beverages during controlled product use?:	EXBEV	Categorical yes/no (dichotomous)	3	

EX=Exposure

CEG_P1_078

Part B - Controlled Usual Brand Dosing Log at Day 4,Day 5,Day 6

EXTRT=USUAL BRAND CIGARETTES

EXGRPID=PART B

EXROUTE=RESPIRATORY (INHALATION)

EXLOC=RESPIRATORY SYSTEM

CONTROLLED USUAL BRAND (MENTHOL) PRODUCT USE LOG

(Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))

Time part of EXSTDTC

Date of Visit: [1] **Date part of EXSTDTC/EXENDTC**

EXSPID

Session Start Time: [2] **Time part of EXSTDTC**

	Puff: [3]	Puff Begin: [4]	Puff End: [5]	Missed Puff: [6]	If yes, provide reason: [7]
1	Puff 1			Yes No	
2	Puff 2			Yes No	
3	Puff 3			Yes No	
4	Puff 4			Yes No	
5	Puff 5			Yes No	
6	Puff 6			Yes No	
7	Puff 7			Yes No	
8	Puff 8			Yes No	
9	Puff 9			Yes No	
10	Puff 10			Yes No	

Did the subject consume any beverages during controlled product use? Yes No [8]

SUPPEX.QVAL, when QNAM is EXBEV

Time part of EXENDTC

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXDATVLN	Date	11	
[2]	Session Start Time:	EXSTTIM	Time	5	
[3]	Puff:	EXPFF	Categorical select one (nominal)	7	Puff 1 Puff 2 Puff 3 Puff 4 Puff 5 Puff 6 Puff 7 Puff 8 Puff 9 Puff 10
[4]	Puff Begin:	EXPFBG	Time	8	
[5]	Puff End:	EXPFEN	Time	8	
[6]	Missed Puff:	EXMISPF	Categorical yes/no (dichotomous)	3	
[7]	If yes, provide reason:	EXCOM	Text or Any Value	200	
[8]	Did the subject consume any beverages during controlled product use?	EXBEVB	Categorical yes/no (dichotomous)	3	

EX=Exposure

CEG_P1_078

Part B - Uncontrolled Usual Brand Dosing Log at Day 4,Day 5,Day EXROUTE=ORAL EXLOC=ORAL CAVITY EXGRPID=PART B

UNCONTROLLED USUAL BRAND (MENTHOL) PRODUCT USE LOG

(Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)

EXCAT=Session

Date of Visit: [1] Date part of EXSTDTC/EXENDTC

Session Start Time: [2] Time part of EXSTDTC

Session End Time: [3] Time part of EXENDTC

EXCAT=Inhalation

Inhalation Begin: **[4]** Time Unknown: **[5]** Inhalation End: **[6]** Time Unknown: **[7]**

1

Time part of EXSTDTC

Time part of EXENDTC

More rows: 1 5 10

Did the subject consume any beverages during uncontrolled product use? Yes No **[8]** SUPPEX.QVAL when QNAM=EXBEV

Session Total Inhalations: **[9]** EXDOSE/EXDOSU

EXCAT=CONTROLLED EXTRT=Very Low Nicotine Cigarettes

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXDATB	Date	11	
[2]	Session Start Time:	EXSRTTIM	Time	5	
[3]	Session End Time:	EXENDTIM	Time	5	
[4]	Inhalation Begin:	EXINHBG	Time	8	
[5]	Time Unknown:	EXTIMUNK	Categorical yes/no (dichotomous)	3	
[6]	Inhalation End:	EXINEN	Time	8	
[7]	Time Unknown:	EXTIMUNK5	Categorical yes/no (dichotomous)	3	
[8]	Did the subject consume any beverages during uncontrolled product use?	EXBEVB	Categorical yes/no (dichotomous)	3	
[9]	Session Total Inhalations:	EXINTOT	Number (continuous)	15	

For Annotations see Page 79

CEG_P1_078

Part B - Controlled VLN Dosing Log at Day 4,Day 5,Day 6

CONTROLLED VERY LOW NICOTINE (VLN) (MENTHOL) PRODUCT USE LOG

(Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))

Date of Visit: [ ] **[1]**

Session Start Time: [ ] **[2]**

	Puff: **[3]**	Puff Begin: **[4]**	Puff End: **[5]**	Missed Puff: **[6]**	If yes, provide reason: **[7]**
1	Puff 1			○ Yes ○ No	
2	Puff 2			○ Yes ○ No	
3	Puff 3			○ Yes ○ No	
4	Puff 4			○ Yes ○ No	
5	Puff 5			○ Yes ○ No	
6	Puff 6			○ Yes ○ No	
7	Puff 7			○ Yes ○ No	
8	Puff 8			○ Yes ○ No	
9	Puff 9			○ Yes ○ No	
10	Puff 10			○ Yes ○ No	

Did the subject consume any beverages during controlled product use? ○ Yes ○ No **[8]**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXDATVLN	Date	11	
[2]	Session Start Time:	EXSTTIM	Time	5	
[3]	Puff:	EXPFF	Categorical select one (nominal)	7	Puff 1 Puff 2 Puff 3 Puff 4 Puff 5 Puff 6 Puff 7 Puff 8 Puff 9 Puff 10
[4]	Puff Begin:	EXPFBG	Time	8	
[5]	Puff End:	EXPFEN	Time	8	
[6]	Missed Puff:	EXMISPF	Categorical yes/no (dichotomous)	3	
[7]	If yes, provide reason:	EXCOM	Text or Any Value	200	
[8]	Did the subject consume any beverages during controlled product use?	EXBEVB2	Categorical yes/no (dichotomous)	3	

For Annotations see Page 81

CEG_P1_078

Part B - Uncontrolled VLN Dosing Log at Day 4,Day 5,Day 6

UNCONTROLLED VERY LOW NICOTINE (VLN) (MENTHOL) PRODUCT USE LOG

(Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)

Date of Visit: [ ] **[1]**

Session Start Time: [ ] **[2]**

Session End Time: [ ] **[3]**

	Inhalation Begin: **[4]**	Time Unknown: **[5]**	Inhalation End: **[6]**	Time Unknown: **[7]**
1	[ ]	☐	[ ]	☐

More rows: 1 5 10

Did the subject consume any beverages during uncontrolled product use? ○ Yes ○ No **[8]**

Session Total Inhalations: [ ] **[9]**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Visit:	EXDATB	Date	11	
[2]	Session Start Time:	EXSRTTIM	Time	5	
[3]	Session End Time:	EXENDTIM	Time	5	
[4]	Inhalation Begin:	EXINHBG	Time	8	
[5]	Time Unknown:	EXTIMUNK	Categorical yes/no (dichotomous)	3	
[6]	Inhalation End:	EXINEN	Time	8	
[7]	Time Unknown:	EXTIMUNK2	Categorical yes/no (dichotomous)	3	
[8]	Did the subject consume any beverages during uncontrolled product use?	EXBEVB	Categorical yes/no (dichotomous)	3	
[9]	Session Total Inhalations:	EXINTOT	Number (continuous)	15	

QS=Questionnaire

CEG_P1_078

1st Use - Tobacco/Nicotine Questionnaire at Day 4,Day 5,Day 6

Was Questionnaire performed at all time points: ○ Yes ○ No **[1]**

QSTPT

Use: ○ 1st Use **[2]** **QSSCAT**

Time point: **[3]** Completed: **[4]**

1 ▼ ○ Yes ○ No **QSORRES/QSSTRESC**

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Questionnaire performed at all time points:	QSPERF	Categorical yes/no (dichotomous)	3	
[2]	Use:	QSUSE	Categorical select one (nominal)	7	
[3]	Time point:	QSTMPT	Categorical select one (nominal)	9	Predose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN	Categorical yes/no (dichotomous)	3	

For Annotations, See Page 87

CEG_P1_078

2nd Use - Tobacco/Nicotine Questionnaire at Day 4,Day 5,Day 6

Was Questionnaire performed at all time points: ○ Yes ○ No **[1]**

Use: ○ 2nd Use **[2]**

	Time point: **[3]**	Completed: **[4]**
1		○ Yes ○ No

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Questionnaire performed at all time points:	QSPERF_1	Categorical yes/no (dichotomous)	3	
[2]	Use:	QSUSE_1	Categorical select one (nominal)	7	
[3]	Time point:	QSTMPT_1	Categorical select one (nominal)	9	Predose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN_1	Categorical yes/no (dichotomous)	3	

For Annotations, See Page 87

CEG_P1_078

1st Use - Direct Effects of Product Questionnaire at Day 4,Day 5,Day 6

Was Questionnaire performed at all time points: ○ Yes ○ No **[1]**

Use: ○ 1st Use **[2]**

Time point: **[3]** Completed: **[4]**

1 [▼] ○ Yes ○ No

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Questionnaire performed at all time points:	QSPERF_2	Categorical yes/no (dichotomous)	3	
[2]	Use:	QSUSE_2	Categorical select one (nominal)	7	
[3]	Time point:	QSTMPT_2	Categorical select one (nominal)	9	Predose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN_2	Categorical yes/no (dichotomous)	3	

For Annotations, See Page 87

CEG_P1_078

2nd Use - Direct Effects of Product Questionnaire at Day 4,Day 5,Day 6

Was Questionnaire performed at all time points: ○ Yes ○ No **[1]**

Use: ○ 2nd Use **[2]**

	Time point: **[3]**	Completed: **[4]**
1		○ Yes ○ No

More rows: 1 5 10

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Questionnaire performed at all time points:	QSPERF_3	Categorical yes/no (dichotomous)	3	
[2]	Use:	QSUSE_3	Categorical select one (nominal)	7	
[3]	Time point:	QSTMPT_3	Categorical select one (nominal)	9	Predose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN_3	Categorical yes/no (dichotomous)	3	

[NOT SUBMITTED]

CEG_P1_078

Use Product Again - VAS at Day 1,Day 2,Day 3

Was Questionnaire performed?

- ○ Yes **[1]**
- ○ No

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Questionnaire performed?	QSPERF	Categorical yes/no (dichotomous)	3	

For Annotations, See Page 87

CEG_P1_078

Use Product Again - VAS at Day 4,Day 5,Day 6

Was Questionnaire performed?
- ○ Yes **[1]**
- ○ No

Use:
- ○ 1st Use **[2]**
- ○ 2nd Use

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was Questionnaire performed?	QSPERF	Categorical yes/no (dichotomous)	3	
[2]	Use:	QSUSE	Categorical select one (nominal)	7	

EG=ECG Test Results

CO=COMMENTS

CEG_P1_078

ECG Test Results at Screening,Day 6,Early Term,Unscheduled Visit

EGSTAT=NOT DONE where EGTESTCD=VSALL

NOT SUBMITTED

Was the ECG performed? ○ Yes [1] ○ No

Repeat ECG? ○ Yes [2] ○ No

Date: [3]

Date Part of EGDTC

Visit: [4]

[NOT SUBMITTED]

EGTESTCD

EGTEST

	Time: [5]	Time Unknown: [6]	Position: [7]	VR: (msec) [8]	PR Interval: (msec) [9]	QRS Interval: (msec) [10]	QT Interval: (msec) [11]	QTcB Interval: [12]	QTcF: (msec) [13]	Clinical Significance as per MD: [14]	If Abnormal and Clinically Significant, please specify abnormalities: [15]
1		☐								○ NORMAL ○ ABNORMAL NCS ○ ABNORMAL CS	

EGPOS

Time Part of EGDTC

EGORRES

EGORRESU

COVAL

EGORRES when EGTESTCD =INTP

EGEVAL=INVESTIGATOR

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Was the ECG performed?	EGYN	Categorical yes/no (dichotomous)	3	
[2]	Repeat ECG?	EGPERFR	Categorical yes/no (dichotomous)	3	
[3]	Date:	EGDAT	Date	11	
[4]	Visit:	EGVIS	Categorical select one (nominal)	10	Screening Day 6 Early Term N/A
[5]	Time:	EGTIM	Time	5	
[6]	Time Unknown:	EGTMNK	Categorical yes/no (dichotomous)	3	
[7]	Position:	EGPOS	Categorical select one (nominal)	6	SUPINE
[8]	VR:	EGVR	Number (continuous)	15	
[9]	PR Interval:	EGPR	Number (continuous)	15	
[10]	QRS Interval:	EGQRS	Number (continuous)	15	
[11]	QT Interval:	EGQT	Number (continuous)	15	
[12]	QTcB Interval:	EGQTCB	Number (continuous)	15	
[13]	QTcF:	EGQTCF	Number (continuous)	15	
[14]	Clinical Significance as per MD:	EGCLSIG	Categorical select one (nominal)	12	
[15]	If Abnormal and Clinically Significant, please specify abnormalities:	EGCOM	Text or Any Value	200	

DS=Disposition

DM=Demographics

CEG_P1_078

Randomization at Day 1,Day 4

DSSTDTC

Date of Randomization: [1]

Randomization Number: [2]

Sequence group: [3]

[NOT SUBMITTED]

DSDECOD/DSTERM=RANDOMIZED

SUPPDM.QVAL where QNAM=RANDANO or RANDBNO depending if it's randomized on Day 1 or Day 4 respectively

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Date of Randomization:	DSRDAT	Date	11	
[2]	Randomization Number:	DSNUM	Text or Any Value	200	
[3]	Sequence group:	DSRNGRP	Categorical select one (nominal)	3	ABC BCA CAB

AE=Adverse Events

CEG_P1_078

Adverse Events at All Visits

Were any Adverse Events experienced? Yes No **[1]**

	AE Identifier: **[2]**	Adverse Event Term: **[3]**	Is this an SAE? **[4]**	Severity: **[5]**	Frequency: **[6]**	Action Taken with Study Treatment: **[7]**	Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) **[8]**	Did the AE result in withdrawal from study? **[9]**	Relationship to Investigational Product: **[10]**	Was this AE a result of Study Medication error? **[11]**	Outcome: **[12]**	Onset Date: **[13]**	Onset Time: **[14]**	Time Unknown: **[15]**	AE Ongoing? **[16]**	End Date: **[17]**	End Time: **[18]**	Time Unknown: **[19]**
1			Yes No				Yes No	Yes No		Yes No								

More rows: 1 5 10

AESPID

AETERM

AESER

AESEV

AEACN

AEPATT

AECONTRT

AEREL

AEOUT

Date Part of AEENDTC

TimePart of AESTDTC

AEENRF

Date Part of AEENDTC

SUPPAE.QVAL when QNAM=AEDIS

SUPPAE.QVAL when QNAM=AEMEDERR

Time Part of AEENDTC

For Annotations see Page 101

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Were any Adverse Events experienced?	AEYN	Categorical yes/no (dichotomous)	3	
[2]	AE Identifier:	AESPID	Number (continuous)	15	
[3]	Adverse Event Term:	AETERM	Text or Any Value	200	
[4]	Is this an SAE?	AESER	Categorical yes/no (dichotomous)	3	
[5]	Severity:	AESEV	Categorical select one (nominal)	8	MILD MODERATE SEVERE
[6]	Frequency:	AEFREQ	Categorical select one (nominal)	14	Single Episode Intermittent Continuous
[7]	Action Taken with Study Treatment:	AEACN	Categorical select one (nominal)	24	No Action Taken Stopped Temporarily Permanently Discontinued
[8]	Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form)	AECONTRT	Categorical yes/no (dichotomous)	3	
[9]	Did the AE result in withdrawal from study?	AEDIS	Categorical yes/no (dichotomous)	3	
[10]	Relationship to Investigational Product:	AEREL	Categorical select one (nominal)	16	Probably Related Possibly Related Unlikely Related Unrelated
[11]	Was this AE a result of Study Medication error?	AETEAE	Categorical yes/no (dichotomous)	3	
[12]	Outcome:	AEOUT	Categorical select one (nominal)	28	Resolved Resolved with Sequelae Unresolved/Ongoing Unresolved/Lost to Follow-Up Fatal
[13]	Onset Date:	AESTDAT	Date	11	
[14]	Onset Time:	AESTTIM	Time	5	
[15]	Time Unknown:	AESTTMNK	Categorical yes/no (dichotomous)	3	
[16]	AE Ongoing?	AEONGO	Categorical yes/no (dichotomous)	3	
[17]	End Date:	AEENDAT	Date	11	
[18]	End Time:	AEENTIM	Time	5	
[19]	Time Unknown:	AEENTMNK	Categorical yes/no (dichotomous)	3	

DS=Disposition

CO=COMMENTS

CEG_P1_078

End of Study at Day 6,Early Term

DSCAT=DISPOSITION EVENT

Visit Date [1] [NOT SUBMITTED]

Date of Completion or Discontinuation: [2] DSSTDTC

Date of Last Dose of Study Medication: [3] SUPPDS.QVAL where QNAM=DSDTCMED

Did the subject complete the study? ○ Yes ○ No **[4]** DSTERM/DSDECOD=COMPLETED, when Y

If No, please mark the PRIMARY reason for discontinuation:

Primary reason for study discontinuation:

DSTERM/DSDECOD

- ○ Entered the study in violation of the protocol **[5]**
- ○ Safety reasons, including AEs
- ○ Use of unacceptable concomitant medication(s)
- ○ Non-compliance or major protocol violation
- ○ It is not considered in the best interest of the subject to continue
- ○ Pregnancy
- ○ Positive UDS or alcohol test
- ○ Administrative reasons (e.g., termination of enrollment or study)
- ○ Difficulties with blood collection
- ○ Other, specify:

If Other, please specify: DSTERM when DSDECOD=OTHER **[6]**

Additional Comments: COVAL where COREF=END OF STUDY **[7]**

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit Date	DSVDAT	Date	11	
[2]	Date of Completion or Discontinuation:	DSDAT	Date	11	
[3]	Date of Last Dose of Study Medication:	DSDOSDAT	Date	11	
[4]	Did the subject complete the study?	DSCOMYN	Categorical yes/no (dichotomous)	3	
[5]	Primary reason for study discontinuation:	DSDECOD	Categorical select one (nominal)	68	
[6]	If Other, please specify:	DSTERM	Text or Any Value	200	
[7]	Additional Comments:	DSCOM	Text or Any Value	250	

PC=Pharmacokinetic Concentrations

CEG_P1_078

1st Use - PK Blood Sampling at Day 4,Day 5,Day 6

SUPPPC.QVAL where QNAM=USE

Use: [1]

[NOT SUBMITTED]

PCTPT **PCDTC** **PCSTAT** **SUPPPC.QVAL where QNAM=PKCODE**

	Timepoint: [2]	Date: [3]	Time: [4]	Not Done: [5]	Time Unknown [6]	Comments: [7]
1	Predose			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
2	2 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
3	5 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
4	7 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
5	10 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
6	12 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
7	15 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note

CEG_P1_078

8	20 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
9	30 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
10	45 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
11	60 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
12	90 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
13	120 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
14	150 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
15	180 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note

CEG_P1_078

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Use:	PKUSE	Categorical select one (nominal)	22	1st Use (Morning Draw)
[2]	Timepoint:	PKTPT	Categorical select one (nominal)	10	Predose 2 minute 5 minute 7 minute 10 minute 12 minute 15 minute 20 minute 30 minute 45 minute 60 minute 90 minute 120 minute 150 minute 180 minute
[3]	Date:	PKDAT	Date	11	
[4]	Time:	PKTIM	Time	5	
[5]	Not Done:	PKSTAT	Categorical yes/no (dichotomous)	3	
[6]	Time Unknown	PKACTNK	Categorical yes/no (dichotomous)	3	
[7]	Comments:	PKCODE	Categorical select multiple	48	

For Annotations, See Page 107

CEG_P1_078

2nd Use - PK Blood Sampling at Day 4,Day 5,Day 6

Use: [1]

	Timepoint: [2]	Date: [3]	Time: [4]	Not Done: [5]	Time Unknown [6]	Comments: [7]
1	Predose			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
2	2 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
3	5 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
4	7 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
5	10 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
6	12 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
7	15 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note

CEG_P1_078

8	20 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
9	30 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
10	45 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
11	60 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
12	90 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
13	120 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
14	150 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note
15	180 minute			☐	☐	☐A - Late due to difficult collection ☐B - Late due to previous procedure ☐C - Early Collection; please specify in Lab Note ☐D - Other; please specify in Lab Note

CEG_P1_078

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Use:	PKUSE	Categorical select one (nominal)	24	2nd Use (Afternoon Draw)
[2]	Timepoint:	PKTPT	Categorical select one (nominal)	10	Predose 2 minute 5 minute 7 minute 10 minute 12 minute 15 minute 20 minute 30 minute 45 minute 60 minute 90 minute 120 minute 150 minute 180 minute
[3]	Date:	PKDAT	Date	11	
[4]	Time:	PKTIM	Time	5	
[5]	Not Done:	PKSTAT	Categorical yes/no (dichotomous)	3	
[6]	Time Unknown	PKACTNK	Categorical yes/no (dichotomous)	3	
[7]	Comments:	PKCODE	Categorical select multiple	48	

CM=Concomitant Medications

CEG_P1_078

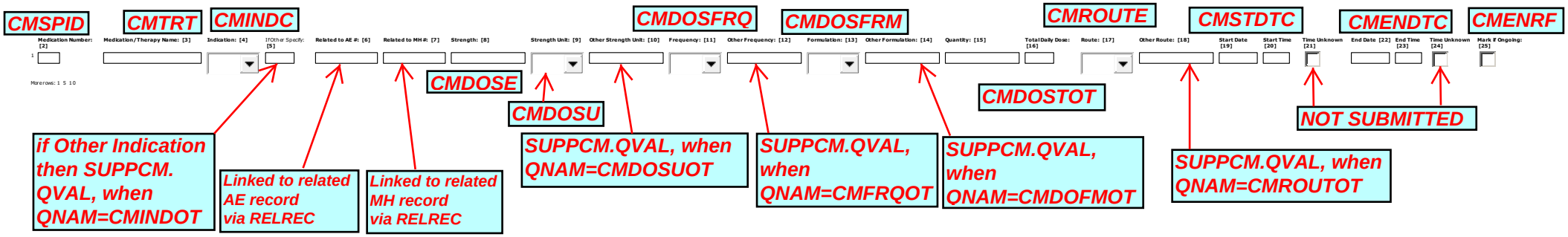
Concomitant Medications at All Visits

[NOT SUBMITTED]

Were there any medications or therapies taken during the protocol-specified window?

Yes **[1]**

No



CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Were there any medications or therapies taken during the protocol-specified window?	CMYN	Categorical yes/no (dichotomous)	3	
[2]	Medication Number:	CMSPID	Number (continuous)	15	
[3]	Medication/Therapy Name:	CMTRT	Text or Any Value	200	
[4]	Indication:	CMINDC	Categorical select one (nominal)	15	Medical History Adverse Event Other
[5]	If Other Specify:	CMOTH	Text or Any Value	4000	
[6]	Related to AE #:	CMAENO	Number (continuous)	15	
[7]	Related to MH #:	CMMHNO	Number (continuous)	15	
[8]	Strength:	CMDOSE	Text or Any Value	200	
[9]	Strength Unit:	CMDOSU	Categorical select one (nominal)	7	mg mL mcg L IU g oz Other Unknown
[10]	Other Strength Unit:	CMDOSUOT	Text or Any Value	200	
[11]	Frequency:	CMDOSFRQ	Categorical select one (nominal)	19	DAILY ONCE TWICE PER DAY THREE TIMES PER DAY FOUR TIMES PER DAY EVERY MONTH EVERY OTHER DAY UNKNOWN AS NEEDED OTHER
[12]	Other Frequency:	CMDOFQOT	Text or Any Value	200	
[13]	Formulation:	CMDOSFRM	Categorical select one (nominal)	11	TABLET CAPSULE OINTMENT SUPPOSITORY AEROSOL SPRAY SUSPENSION PATCH GEL CREAM POWDER UNKNOWN OTHER
[14]	Other Formulation:	CMDOFMOT	Text or Any Value	200	
[15]	Quantity:	CMQUANT	Text or Any Value	4000	
[16]	Total Daily Dose:	CMTOTDOS	Number (continuous)	15	

CEG_P1_078

[17]	Route:	CMROUTE	Categorical select one (nominal)	16	AURICULAR (OTIC) BUCCAL CONJUNCTIVAL CUTANEOUS INTRADERMAL INTRAMUSCULAR INTRAOCULAR INTRASINAL INTRAUTERINE INTRAVENOUS NASAL ORAL RECTAL SUBCUTANEOUS SUBLINGUAL TOPICAL VAGINAL UNKNOWN OTHER
[18]	Other Route:	CMROUTEO	Text or Any Value	200	
[19]	Start Date	CMSTDAT	Date	11	
[20]	Start Time	CMSTTIM	Time	5	
[21]	Time Unknown	CMSTTNK	Categorical yes/no (dichotomous)	3	
[22]	End Date	CMENDAT	Date	11	
[23]	End Time	CMENTIM	Time	5	
[24]	Time Unknown	CMENTNK	Categorical yes/no (dichotomous)	3	
[25]	Mark if Ongoing:	CMONGO	Categorical yes/no (dichotomous)	3	

For Annotations see Page 65

CEG_P1_078

Unscheduled Vital Signs at Unscheduled Visit

Visit: [1]

Were vital signs measured? ○ Yes [2] ○ No

Time Seated: [3] Time Seated Unknown: [4]

Date: [5] Time Taken: [6] Time Unknown: [7]

	Assessment: [8]	Not done: [9]	Result: [10]	Unit: [11]	MD Safety Review: [12]
1	Oral Temperature	☐		C	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
2	Systolic Blood Pressure	☐		mmHg	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
3	Diastolic Blood Pressure	☐		mmHg	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
4	Pulse Rate	☐		beats/min	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS
5	Respirations	☐		breaths/min	○ WITHIN NORMAL RANGE ○ OUT-OF-RANGE, ABNORMAL NCS ○ OUT-OF-RANGE, ABNORMAL CS

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit:	VSVIS	Categorical select one (nominal)	17	Screening Day -1 Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Early Termination N/A
[2]	Were vital signs measured?	VSPERF	Categorical yes/no (dichotomous)	3	
[3]	Time Seated:	VS1TIMS	Time	5	
[4]	Time Seated Unknown:	VSTIMSUN	Categorical yes/no (dichotomous)	3	
[5]	Date:	VSDAT	Date	11	
[6]	Time Taken:	VSTIM	Time	5	
[7]	Time Unknown:	VSTMNK	Categorical yes/no (dichotomous)	3	
[8]	Assessment:	VSTEST	Categorical select one (nominal)	24	Oral Temperature Systolic Blood Pressure Diastolic Blood Pressure Pulse Rate Respirations Heart Rate
[9]	Not done:	VSSTAT	Categorical yes/no (dichotomous)	3	
[10]	Result:	VSORRES	Number (continuous)	15	
[11]	Unit:	VSORRESU	Categorical select one (nominal)	11	C mmHg beats/min breaths/min
[12]	MD Safety Review:	VSCLSIG	Categorical select one (nominal)	26	

SU=Substance Use

CEG_P1_078

Tobacco Use at Screening

	SUTRT	SUDOSFRQ	SUSTDTC	SUENDTC	SUDOSE/SUDOSU			
	Type of tobacco used? **[1]**	Frequency: **[2]**	Start Date: **[3]**	End Date: **[4]**	Yearly Use: (Units) **[5]**	Monthly Use: (Units) **[6]**	Weekly Use: (Units) **[7]**	Daily Use: (Units) **[8]**
1	Cigarette(s)							
2	Cigar(s)							
3	Cigarillo(s)							
4	Chewing Tobacco							
5	Pipe(s)							
6	Nicotine Product(s): (patch, gum, etc)							
7	Electronic Cigarette(s)/E-Vapors							

CEG_P1_078

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Type of tobacco used?	SUTRT	Categorical select one (nominal)	38	Cigarette(s) Cigar(s) Cigarillo(s) Chewing Tobacco Pipe(s) Nicotine Product(s): (patch, gum, etc) Electronic Cigarette(s)/E-Vapors
[2]	Frequency:	SUFRQ	Categorical select one (nominal)	7	Never Current Former
[3]	Start Date:	SUSTDAT	Date	11	
[4]	End Date:	SUENDAT	Date	11	
[5]	Yearly Use:	SUYRUS	Number (continuous)	15	
[6]	Monthly Use:	SUMONUS	Number (continuous)	15	
[7]	Weekly Use:	SUWKUS	Number (continuous)	15	
[8]	Daily Use:	SUDYUS	Number (continuous)	15	