

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
- Part A - Usual Brand Dose Log
- Part A - VLN Dosing Log
- Part A - Nicorette Dosing Log
- Randomization
- 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 - Uncontrolled Usual Brand Dosing Log

Part B - Controlled 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

1st Use - PK Blood Sampling

2nd Use - PK Blood Sampling

Use Product Again - VAS

Day 5

Visit Date

Part B - Controlled Nicorette Dosing Log

Part B - Uncontrolled Nicorette Dosing Log

Part B - Uncontrolled Usual Brand Dosing Log

Part B - Controlled 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

1st Use - PK Blood Sampling

2nd Use - PK Blood Sampling

Use Product Again - VAS

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
ECG Test Results
1st Use - Tobacco/Nicotine Questionnaire
2nd Use - Tobacco/Nicotine Questionnaire
1st Use - Direct Effects of Product Questionnaire
2nd Use - Direct Effects of Product Questionnaire
End of Study
1st Use - PK Blood Sampling
2nd Use - PK Blood Sampling
Use Product Again - VAS

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
1st Use - PK Blood Sampling
2nd Use - PK Blood Sampling

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

CEG_P9_153
ICF at Screening

Was the most current IRB approved version of the Informed Consent signed by the subject? Yes [1] **DSDECOD/DSTERM='INFORMED CONSENT OBTAINED'** No

RFICDTC

Date Subject Signed ICF: ICF Version: [3] ICF Version Date: **SUPPDS.QVAL, when QNAM='ICFVRDTC'**
(Original signature) [2] [4]

1

More rows: 1 5 10

DSDTC/DSSTDTC

SUPPDS.QVAL, when QNAM='ICFVRN'

CEG_P9_153

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-P9-153 v2 ICF CEG-P9-153 v3 ICF CEG-P9-153
[4]	ICF Version Date:	DSVDAT	Date	11	

[NOT SUBMITTED]

CEG_P9_153

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_P9_153

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	

CEG_P9_153

INCL/EXCL Criteria Summary at Screening

Does the subject meet all eligibility criteria required by the protocol? Yes [1] No

IECAT=INCLUSION

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

Specify: [2] Number: [3] Comment: [4]

1 Inclusion criteria
 Exclusion criteria

COVAL where COREF='INCLUSION/ EXCLUSION CRITERIA'

More rows: 1 5 10

IECAT=EXCLUSION

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

CEG_P9_153

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	

CEG_P9_153
Demographics at Screening

Visit Date: [1] **DMDTC**

Date of Birth: [2] **BRTHDTC**

Age: [3] **AGE**

Age Unit: [4] **AGEU**

Gender: M [5] **SEX**
 F

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

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

Other, Specify: [8] **SUPPDM.QVAL when QNAM='RACEOTH'**

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

CEG_P9_153

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	

CEG_P9_153

Medical History at Screening

MHCAT=GENERAL

Does the subject have any relevant medical or surgical history (including drug allergies)? Yes [1] **[NOT SUBMITTED]** No

MHSPID

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

MHTERM

MHSTDTC

MHENDTC

MHENRF

SUPPMH.QVAL when QNAM='MHCLSIG'

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 Significant

Clinically Significant

MHSCAT

SUPPMH.QVAL when QNAM='MHOTHSP'

More rows: 1 5 10

Does the subject self-report the desire to smoke within approximately 30 minutes of waking? [11]

SUPPMH.QVAL when QNAM='MHSMK'

Does the subject have a history of recreational drug use? [12]

SUPPMH.QVAL when QNAM='MHRECUSE'

CEG_P9_153

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

CEG_P9_153

Female Contraceptive Method at Screening

RPCAT=FEMALE CONTRACEPTIVE METHOD

Visit Date [] [1] RPDTC

Childbearing Potential:

- CHILDBEARING POTENTIAL [2]
- NON-CHILDBEARING POTENTIAL

RPTTESTCD=CHILDPOT

RPTTEST=Childbearing Potential

RPORRES should be "Yes" if Childbearing Potential and "No" if Non-Childbearing Potential

Is subject considered post-menopausal?

- Yes [3]
- No

RPORRES when RPTTESTCD='MENOSTAT'

Last menses: [] [4]

RPORRES when RPTTESTCD='LMPSTDTC'

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

1 []
More rows: 1 5 10

RPORRES when RPTTESTCD=BCMETHOD

[]

SUPPRP.QVAL when QNAM='BCMSTDTC'

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

1 []
More rows: 1 5 10

RPORRES when RPTTESTCD=BCMETHOD

[]

SUPPRP.QVAL when QNAM='SCPRODAT'

CEG_P9_153

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-oophorectomy or bilateral oophorectomy Tubal Ligation Hysterectomy Hysterectomy with bilateral salpingo-oophorectomy Post-menopausal
[8]	Procedure Date:	SCPRODAT	Date	11	

CEG_P9_153

Complete Physical Examination at Screening

PECAT=COMPLETE

Was the physical examination performed? Yes No [1] PESTAT='NOT DONE' when PETESTCD='PEALL'

Examination Date: [2] Datepart of PEDTC

Completion Time: [3] Timepart of PEDTC

PETEST

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

Body System Examined: [4]

Not done: [5] If Other, please specify: [6]

Examination Result: [7] Abnormal Findings: [8]

1	GENERAL APPEARANCE	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
2	HEENT	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
3	NECK/THYROID	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
4	CARDIOVASCULAR	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
5	RESPIRATORY	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
6	GASTROINTESTINAL	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
7	NEUROLOGICAL	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
8	MUSCULOSKELETAL/EXTREMITIES	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	
9	SKIN	<input type="checkbox"/>	<input type="text"/>	<input type="radio"/> NORMAL	<input type="text"/>
				<input type="radio"/> ABNORMAL NCS	
				<input type="radio"/> ABNORMAL CS	

PESTAT

SUPPE.QVAL when QNAM='PETESTOT'

CEG_P9_153

10 OTHER ▾

For Annotations see Page 17

- NORMAL
- ABNORMAL NCS
- ABNORMAL CS

CEG_P9_153

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

PE=Physical Examination

Visit: [dropdown] [1] [NOT SUBMITTED]

Was the physical examination performed? Yes No [2]

Examination Date: [text] [3]

Completion Time: [text] [4]

Body System Examined: [5] Not done: [6] If Other, please specify: [7] Examination Result: [8] Abnormal Findings: [9]

Body System Examined: [5]	Not done: [6]	If Other, please specify: [7]	Examination Result: [8]	Abnormal Findings: [9]
1 GENERAL APPEARANCE [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
2 HEENT [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
3 NECK/THYROID [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
4 CARDIOVASCULAR [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
5 RESPIRATORY [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
6 GASTROINTESTINAL [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
7 NEUROLOGICAL [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
8 MUSCULOSKELETAL/EXTREMITIES [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL <input type="radio"/> ABNORMAL NCS <input type="radio"/> ABNORMAL CS	[text]
9 SKIN [dropdown]	<input type="checkbox"/>	[text]	<input type="radio"/> NORMAL	[text]

For Annotations see Page 17

CEG_P9_153

10 OTHER ▾

- ABNORMAL NCS
- ABNORMAL CS

- NORMAL
- ABNORMAL NCS
- ABNORMAL CS

CEG_P9_153

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	

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] Examination Results: [6] Abnormal Findings: [7]

1 Normal
 Abnormal NCS
 Abnormal CS

2 Normal
 Abnormal NCS
 Abnormal CS

3 Normal
 Abnormal NCS
 Abnormal CS

4 Normal
 Abnormal NCS
 Abnormal CS

5 Normal
 Abnormal NCS
 Abnormal CS

If Other, please specify: [8]

CEG_P9_153

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]	Examination Results:	PEORRES	Categorical select one (nominal)	12	
[7]	Abnormal Findings:	PECLSIG	Text or Any Value	200	
[8]	If Other, please specify:	PEOTHSP	Text or Any Value	200	

CEG_P9_153

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] 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

If Other, please specify: [] [9]

CEG_P9_153

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
[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]	Examination Results:	PEORRES	Categorical select one (nominal)	12	
[8]	Abnormal Findings:	PECLSIG	Text or Any Value	200	
[9]	If Other, please specify:	PEOTHSP	Text or Any Value	200	

CEG_P9_153

Height, Weight and BMI at Screening

Was the assessment performed?

- Yes [1]
- No

VSSTAT='NOT DONE' when VSTESTCD='VSALL'

Visit Date:

[2] **VSDTC**

Height:

cm [3]

VSORRES/VSORRESU when VSTESTCD='HEIGHT'

Weight:

kg [4]

VSORRES/VSORRESU when VSTESTCD='WEIGHT'

VSTEST

BMI:

kg/m² [5]

VSORRES/VSORRESU when VSTESTCD='BMI'

CEG_P9_153

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:	VSWG	Number (continuous)	15	
[5]	BMI:	VSBMI	Number (continuous)	15	

LBCAT=SEROLOGY

Was the laboratory evaluation performed?

Yes [1]

LBSTAT='NOT DONE' when LBTESTCD='LBALL'

No

LBOTC

Date of collection:

Time of Collection:

Time Unknown:

[2]

[3]

[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 QNAM='LBCLSIG'

More rows: 1 5 10

CEG_P9_153

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	

CEG_P9_153

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_P9_153

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	

CEG_P9_153

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_P9_153

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	

CEG_P9_153

Serum Pregnancy Test at Unscheduled Visit

Visit: [1]

[NOT SUBMITTED]

Was Serum Pregnancy Test performed? Yes [2]

No

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

CEG_P9_153

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	

CEG_P9_153

Urine Pregnancy Test at Day -1

LBCAT=PREGNANCY

LBTESTCD=HCG

LBSPEC=URINE

Was Urine Pregnancy Test performed?

Yes [1]

LBSTAT='NOT DONE' when LBTESTCD='LBALL'

No

LBDTC

Date of collection:

Time of Collection:

Time Unknown:

[NOT SUBMITTED]

[2]

[3]

[4]

CEG_P9_153

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	

CEG_P9_153

Urine Pregnancy Test at Unscheduled Visit

Visit: [1]

[NOT SUBMITTED]

Was Urine Pregnancy Test performed? Yes [2]

No

Date of collection: [3]

Time of Collection: [4]

Time Unknown: [5]

CEG_P9_153

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	

CEG_P9_153

UDS and Alcohol Laboratory Evaluation at Screening,Day -1

LBCAT=URINE DRUG SCREEN

LB=Laboratory Test Results

Was the laboratory evaluation performed?

- Yes [1]
- No

LBSTAT='NOT DONE' when LBTESTCD='LBALL'

LBDC

Date of collection:

Time of Collection:

Time Unknown:

[2]

[3]

[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 QNAM='LBCLSIG'

More rows: 1 5 10

CEG_P9_153

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	

CEG_P9_153

UDS and Alcohol Laboratory 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: [8]

1 NCS CS

More rows: 1 5 10

CEG_P9_153

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	

CEG_P9_153

Cotinine Evaluation at Screening **LBCAT=COTININE**

Was the laboratory evaluation performed? Yes No [1] **LBSTAT='NOT DONE' when LBTESTCD='LBALL'**

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

LBDTC

Is the result within range? Yes [5] No **LBNRIND**

LBTEST

Test Name: [6] Clinical Significance as per MD: [7] **SUPPLB.QVAL when QNAM='LBCLSIG'**

1 NCS CS

CEG_P9_153

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	

CEG_P9_153

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 NCS CS

CEG_P9_153

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	

CEG_P9_153

Chemistry Laboratory Evaluation at Screening,Day 6

LBCAT=CHEMISTRY

Was the laboratory evaluation performed?

- Yes [1]
- No

LBSTAT='NOT DONE' when LBTESTCD='LBALL'

LBDC

Date of collection:

Time of Collection:

Time Unknown:

[2]

[3]

[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 QNAM='LBCLSIG'

More rows: 1 5 10

CEG_P9_153

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) Gamma-Glutamyl Transferase (GGT) Alkaline Phosphatase Creatine Phosphokinase (CK) Lactate Dehydrogenase (LD)
[7]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

CEG_P9_153

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_P9_153

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) Gamma-Glutamyl Transferase (GGT) Alkaline Phosphatase Creatine Phosphokinase (CK) Lactate Dehydrogenase (LD)
[8]	Clinical Significance as per MD: (Please record an AE for Clinically Significant results)	LBCLSIG	Categorical select one (nominal)	3	

CEG_P9_153

Hematology Laboratory Evaluation at Screening,Day 6

LBCAT=HEMATOLOGY

Was the laboratory evaluation performed?

- Yes [1]
- No

LBSTAT='NOT DONE' when LBTESTCD='LBALL'

LBDTC

Date of collection:

Time of Collection:

Time Unknown:

[2]

[3]

[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 QNAM='LBCLSIG'

More rows: 1 5 10

CEG_P9_153

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	

CEG_P9_153

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_P9_153

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	

CEG_P9_153

Urinalysis Laboratory Evaluation at Screening,Day 6

LBCAT=URINALYSIS

Was the laboratory evaluation performed?

- Yes
- No

[1] LBSTAT=NOT DONE when LBTESTCD='LBALL'

LBDTC

Date of collection:

Time of Collection:

Time Unknown:

[2]

[3]

[4]

[NOT SUBMITTED]

Are all results within normal limits?

- Yes
- No

[5] LBNRIND

LBTEST

Test Name: **[6]**

Clinical Significance as per MD:

(Please record an AE for Clinically Significant results) [7]

SUPPLB.QVAL when QNAM='LBCLSIG'

1

- NCS
- CS

More rows: 1 5 10

CEG_P9_153

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	

CEG_P9_153

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_P9_153

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	

CEG_P9_153

Endocrinology Evaluation at Screening

LBCAT=ENDOCRINOLOGY

Was the laboratory evaluation performed?

Yes [1]

LBSTAT=NO'T DONE' when LBTESTCD='LBALL'

No

LB DTC

Date of collection:

Time of Collection:

Time Unknown:

[NOT SUBMITTED]

[2]

[3]

[4]

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

FSH (Follicle-Stimulating Hormone) ▼

NCS CS

SUPPLB.QVAL when QNAM='LBCLSIG'

CEG_P9_153

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	

CEG_P9_153

Endocrinology 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

CEG_P9_153

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	

CEG_P9_153
Vital Signs at Screening,Day -1,Day 6

Were vital signs measured? Yes [1] **VSTAT='NOT DONE' when VSTESTCD='VSALL'**
 No

SUPPVS.QVAL when QNAM='TIMESPOS'

Repeat vital signs? Yes [2] **[NOT SUBMITTED]**
 No

Time Seated: [3] [4] Time Seated Unknown: **[NOT SUBMITTED]**

Date: [5] **VSDTC** Time Taken: [6] [7] Time Unknown: **[NOT SUBMITTED]**

VSTEST **VSTAT** **VSORRES** **VSORRESU**

Assessment: [8] Not done: [9] Result: [10] Unit: [11]

MD Safety Review: [12] **SUPPVS.QVAL when QNAM='VSCLSIG'**

- 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_P9_153

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	

CEG_P9_153
Vital Signs at Early Term

Visit: [1] **[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

- WITHIN NORMAL RANGE
- OUT-OF-RANGE, ABNORMAL NCS
- OUT-OF-RANGE, ABNORMAL CS

2

- WITHIN NORMAL RANGE
- OUT-OF-RANGE, ABNORMAL NCS
- OUT-OF-RANGE, ABNORMAL CS

3

- WITHIN NORMAL RANGE
- OUT-OF-RANGE, ABNORMAL NCS
- OUT-OF-RANGE, ABNORMAL CS

4

- WITHIN NORMAL RANGE
- OUT-OF-RANGE, ABNORMAL NCS
- OUT-OF-RANGE, ABNORMAL CS

5

- WITHIN NORMAL RANGE
- OUT-OF-RANGE, ABNORMAL NCS
- OUT-OF-RANGE, ABNORMAL CS

CEG_P9_153

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:	VSITIMS	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	

[NOT SUBMITTED]

CEG_P9_153

1st Use - Tobacco/Nicotine 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_P9_153

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	Pre-dose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN	Categorical yes/no (dichotomous)	3	

CEG_P9_153

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

[NOT SUBMITTED]

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_P9_153

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	Pre-dose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN	Categorical yes/no (dichotomous)	3	

[NOT SUBMITTED]

CEG_P9_153

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_P9_153

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	Pre-dose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN	Categorical yes/no (dichotomous)	3	

[NOT SUBMITTED]

CEG_P9_153

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_P9_153

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	Pre-dose 5 minute 15 minute 30 minute 60 minute 90 minute
[4]	Completed:	QSYN	Categorical yes/no (dichotomous)	3	

CEG_P9_153

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

AD LIB USUAL BRAND (NON-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:

**DAORRES when
DATESTCD=DISPAMT**

**DAORRES when
DATESTCD=RETAMT**

Time part of EXSTDTC

Time part of DADTC

Time part of EXENDTC

Time part of DADTC

Date part of EXSTDTC

Date part of EXENDTC

Date part of DADTC

EX=Exposure

DA=Drug Accountability

**EXTRT=USUAL BRAND
CIGARETTES**

EXGRPID=PART A

**EXROUTE=RESPIRATORY
(INHALATION)**

EXLOC=RESPIRATORY SYSTEM

**DASCAT=USUAL BRAND
CIGARETTES**

DAGRPID=PART A

DACAT=STUDY PRODUCT

CEG_P9_153

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	

CEG_P9_153

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

For Annotations see Page 77

AD LIB VERY LOW NICOTINE (VLN) (NON-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

EX=Exposure

DA=Drug Accountability

EXTRT=VERY LOW NICOTINE CIGARETTES

DASCAT=VERY LOW NICOTINE CIGARETTES

CEG_P9_153

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 77

CEG_P9_153

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

EX=Exposure

DA=Drug Accountability

EXROUTE=ORAL

EXLOC=ORAL CAVITY

EXTRT=NICORETTE GUM

DASCAT=NICORETTE GUM

CEG_P9_153

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	

CEG_P9_153

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]

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='EXBEV'

Date part of EXSTDTC

Date part of EXENDTC

EX=Exposure

EXROUTE=ORAL

EXLOC=ORAL CAVITY

EXGRPID=PART B

EXCAT=CONTROLLED

EXTRT=NICORETTE GUM

CEG_P9_153

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 79

EX=Exposure

CEG_P9_153

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

EXCAT=UNCONTROLLED

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_P9_153

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	

CEG_P9_153

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

CO=Comments

EX=Exposure

CONTROLLED USUAL BRAND (NON-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]

Date part of EXSTDTC

Date part of EXENDTC

EXTRT=USUAL BRAND CIGARETTES

EXGRPID=PART B

EXROUTE=RESPIRATORY (INHALATION)

EXLOC=RESPIRATORY SYSTEM

EXCAT=CONTROLLED

EXSPID

Session Start Time: [2] [NOT SUBMITTED]

Puff: [3] Puff Begin: [4] Puff End: [5] Missed Puff: [6] If yes, provide reason: [7]

1	Puff 1			<input type="radio"/> Yes <input type="radio"/> No	
2	Puff 2			<input type="radio"/> Yes <input type="radio"/> No	
3	Puff 3			<input type="radio"/> Yes <input type="radio"/> No	
4	Puff 4			<input type="radio"/> Yes <input type="radio"/> No	
5	Puff 5			<input type="radio"/> Yes <input type="radio"/> No	
6	Puff 6			<input type="radio"/> Yes <input type="radio"/> No	
7	Puff 7			<input type="radio"/> Yes <input type="radio"/> No	
8	Puff 8			<input type="radio"/> Yes <input type="radio"/> No	
9	Puff 9			<input type="radio"/> Yes <input type="radio"/> No	
10	Puff 10			<input type="radio"/> Yes <input type="radio"/> No	

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

COVAL where COREF='INVESTIGATIONAL PRODUCT ADMINISTRATION'

Time part of EXSTDTC

Time part of EXENDTC

EXSTAT=NOT DONE

CEG_P9_153

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	

CEG_P9_153

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

Date part of EXSTDTC

Date part of EXENDTC

EX=Exposure

UNCONTROLLED USUAL BRAND (NON-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]

Time Part of EXSTDTC when EXSCAT=SESSION

Session End Time: [3]

Time Part of EXENDTC when EXSCAT=SESSION

Inhalation Begin: [4] Time Unknown: [5] Inhalation End: [6] Time Unknown: [7] [NOT SUBMITTED]

1

[NOT SUBMITTED]

[NOT SUBMITTED]

Time Part of EXSTDTC when EXSCAT=INHALATION

Time Part of EXENDTC when EXSCAT=INHALATION

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

SUPPEX.QVAL when QNAM=EXBEV related to EXSEQ where EXSCAT=SESSION

Session Total Inhalations: [9]

EXDOSE when EXSCAT=SESSION

EXTRT=USUAL BRAND CIGARETTES

EXGRPID=PART B

EXROUTE=RESPIRATORY (INHALATION)

EXLOC=RESPIRATORY SYSTEM

EXCAT=UNCONTROLLED

CEG_P9_153

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:	EXTIMUNK	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	

CONTROLLED VERY LOW NICOTINE (VLN) (NON-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			<input type="radio"/> Yes <input type="radio"/> No	
2	Puff 2			<input type="radio"/> Yes <input type="radio"/> No	
3	Puff 3			<input type="radio"/> Yes <input type="radio"/> No	
4	Puff 4			<input type="radio"/> Yes <input type="radio"/> No	
5	Puff 5			<input type="radio"/> Yes <input type="radio"/> No	
6	Puff 6			<input type="radio"/> Yes <input type="radio"/> No	
7	Puff 7			<input type="radio"/> Yes <input type="radio"/> No	
8	Puff 8			<input type="radio"/> Yes <input type="radio"/> No	
9	Puff 9			<input type="radio"/> Yes <input type="radio"/> No	
10	Puff 10			<input type="radio"/> Yes <input type="radio"/> No	

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

CEG_P9_153

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:	EXPPF	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 89

EX=Exposure

CEG_P9_153

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

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

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

**EXTRT=VERY LOW NICOTINE
CIGARETTES**

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_P9_153

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:	EXTIMUNK	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	

Was the ECG performed? Yes [1] No

EGSTAT='NOT DONE' when EGTESTCD='VSALL'

Date: [2] Date Part of EGDTC

[NOT SUBMITTED]

Visit: [3]

Time: [4]

Time Unknown: [5]

Position: [6] EGPOS

VR: (msec) [7]

PR Interval: (msec) [8]

QRS Interval: (msec) [9]

QT Interval: (msec) [10]

QTcB Interval: [11]

QTcF: (msec) [12]

Clinical Significance as per MD: [13]

If Abnormal and Clinically Significant, please specify abnormalities: [14]

1 [Time Part of EGDTC]

EGORRES when EGTESTCD='EGVRMN'

EGORRES when EGTESTCD='PRAG'

EGORRES when EGTESTCD='QRSAG'

EGORRES when EGTESTCD='QTAG'

EGORRES when EGTESTCD='QTCBAG'

EGORRES when EGTESTCD='QTCFAG'

- NORMAL
- ABNORMAL NCS
- ABNORMAL CS

[COVAL]

EGORRES when EGTESTCD='INTP'

EGEVAL=INVESTIGATOR

CEG_P9_153

Variable details

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

DS=Disposition

DM=Demographics

CEG_P9_153

Randomization at Day 1,Day 4

Date of Randomization: [1]

DSSTDTC

DSDECOD/DSTERM='RANDOMIZED'

Randomization Number: [2]

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

Sequence Group [3]

[NOT SUBMITTED]

CEG_P9_153

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_P9_153
Adverse Events at All Visits

Were any Adverse Events experienced? Yes No [1] **[NOT SUBMITTED]**

AE Identifier: [2] **AESPID**

Adverse Event Term: [3] **AETERM**

Is this an SAE? [4] **AESER** Yes No

Severity: [5] **AESEV**

Frequency: [6] **AEPATT**

Action Taken with Study Treatment: [7] **AEACN**

Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [8] **AECONTRT** Yes No

Did the AE result in withdrawal from study? [9] **AFRFI** Yes No

Relationship to Investigational Product: [10]

Was this AE a result of Study Medication error? [11] Yes No

Outcome: [12] **AEOUT**

Onset Date: [13] **Date Part of AESTDTC**

Onset Time: [14] **TimePart of AESTDTC**

Time Unknown: [15] **AEENRF**

AE Ongoing? [16] **Date Part of AEENDTC**

End Date: [17] **Time Part of AEENDTC**

End Time: [18] **[NOT SUBMITTED]**

Time Unknown: [19] **[NOT SUBMITTED]**

SUPPAE.QVAL when QNAM='AEDIS'

SUPPAE.QVAL when QNAM='AEMEDERR'

More rows: 1 5 10

CEG_P9_153

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	

CEG_P9_153

End of Study at Day 6, Early Term

DSCAT=DISPOSITION EVENT

DS=Disposition

CO=Comments

Visit Date [1]

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:
- Entered the study in violation of the protocol [5] **DSTERM/DSDECOD**
 - 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 when COREF='END OF STUDY'**
[7]

CEG_P9_153

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Visit Date	DSV DAT	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	

CEG_P9_153

1st Use - PK Blood Sampling at Day 4,Day 5,Day 6,Early Term **PCSPEC=BLOOD**

	Use: <input type="text"/> [1]	[NOT SUBMITTED]			
	PCTPT	PCDTC			
	Timepoint: [2]	Date: [3]	Time: [4]	Not Done: [5]	Time Unknown [6]
					SUPPPC.QVAL when QNAM='PKCODE'
1	Predose	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
				PCSTAT	
					<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
2	2 minute	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
3	5 minute	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
4	7 minute	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
5	10 minute	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
6	12 minute	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
7	15 minute	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
8	20 minute	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/> A - Late due to difficult collection

CEG_P9_153

- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

9 30 minute ▼

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

10 45 minute ▼

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

11 60 minute ▼

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

12 90 minute ▼

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

13 120 minute ▼

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

14 150 minute ▼

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

15 180 minute ▼

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

CEG_P9_153

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	51	

CEG_P9_153

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

Use: [1]

Timepoint: [2] Date: [3] Time: [4] Not Done: [5] Time Unknown [6] Comments: [7]

1	<input type="text" value="Predose"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
2	<input type="text" value="2 minute"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
3	<input type="text" value="5 minute"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
4	<input type="text" value="7 minute"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
5	<input type="text" value="10 minute"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
6	<input type="text" value="12 minute"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
7	<input type="text" value="15 minute"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection <input type="checkbox"/> B - Late due to previous procedure <input type="checkbox"/> C - Early Collection; please specify in Lab Note <input type="checkbox"/> D - No Sample Collected due to difficult collection
8	<input type="text" value="20 minute"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> A - Late due to difficult collection

CEG_P9_153

- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

9 30 minute

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

10 45 minute

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

11 60 minute

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

12 90 minute

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

13 120 minute

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

14 150 minute

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

15 180 minute

- A - Late due to difficult collection
- B - Late due to previous procedure
- C - Early Collection; please specify in Lab Note
- D - No Sample Collected due to difficult collection

CEG_P9_153

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	51	

CEG_P9_153

Concomitant Medications at All Visits

Were there any medications the subject has taken in the past 30 days and throughout the study? Yes [1] No

CMSPID	CM Number: [2]	Medication/Therapy/Procedure: [3]	Indication: [4]	If Other, please specify: [5]	Adverse Event #: [6]	Medical History #: [7]	Strength: [8]	Unit: [9]	If Other, please specify: [10]	Quantity: [11]	Form: [12]	If Other, please specify: [13]	Total Dose: [14]	Unit: [15]	If Other, please specify: [16]	Route: [17]	If Other, please specify: [18]	Frequency: [19]	If Other, please specify: [20]	Start Date: [21]	Start Time: [22]	Time Unknown: [23]	End Date: [24]	End Time: [25]	Time Unknown: [26]	Ongoing?: [27]
	CMTRT	CMINDC																								
1																										

More rows: 1 5 10

Annotations:

- if Other Indication then SUPPCM.QVAL when QNAM='CMINDOT'** (points to Indication field)
- Linked to related AE record via RELREC** (points to Adverse Event # field)
- SUPPCM.QVAL when QNAM='CMAENO'** (points to Adverse Event # field)
- Linked to related MH record via RELREC** (points to Medical History # field)
- SUPPCM.QVAL when QNAM='CMMHNO'** (points to Medical History # field)
- SUPPCM.QVAL when QNAM='CMUNOTH'** (points to If Other, please specify: [10] field)
- CMDOSTXT** (points to Strength field)
- CMDOSTOT** (points to Total Dose field)
- SUPPCM.QVAL when QNAM='CMTOTUN'** (points to Total Dose field)
- CMDOSU** (points to Unit field)
- CMDOSFRM** (points to Form field)
- CMDOSE** (points to Quantity field)
- SUPPCM.QVAL when QNAM='CMDOFMOT'** (points to If Other, please specify: [13] field)
- SUPPCM.QVAL when QNAM='CMROUTOT'** (points to Route field)
- CMROUTE** (points to Route field)
- CMDOSFRQ** (points to Frequency field)
- SUPPCM.QVAL when QNAM='CMFRQOT'** (points to Frequency field)
- CMSTDTC** (points to Start Date field)
- CMENDTC** (points to End Date field)
- CMENRF** (points to Ongoing? field)
- [NOT SUBMITTED]** (points to Time Unknown fields)

CEG_P9_153

Variable details

	Name	Export Name	Type	Max length	Categories
[1]	Were there any medications the subject has taken in the past 30 days and throughout the study?	CMYN	Categorical yes/no (dichotomous)	3	
[2]	CM Number:	CMNUM	Number (continuous)	15	
[3]	Medication/Therapy/Procedure:	CMTRT	Text or Any Value	200	
[4]	Indication:	CMINDC	Categorical select one (nominal)	15	Medical History Adverse Event Other
[5]	If Other, please specify:	CMINDOT	Text or Any Value	4000	
[6]	Adverse Event #:	CMAENUM	Number (continuous)	15	
[7]	Medical History #:	CMMHNUM	Number (continuous)	15	
[8]	Strength:	CMDOSE	Text or Any Value	200	
[9]	Unit:	CMDOSU	Categorical select one (nominal)	7	mg mcg mL L ug IU g oz Other Unknown
[10]	If Other, please specify:	CMDOSOTH	Text or Any Value	4000	
[11]	Quantity:	CMQUANT	Text or Any Value	4000	
[12]	Form:	CMDOSFRM	Categorical select one (nominal)	26	TABLET CAPSULE OINTMENT SUPPOSITORY AEROSOL SPRAY SUSPENSION PATCH GEL CREAM POWDER UNKNOWN CAPLET CHEWING IMPLANT INTRAUTERINE DEVICE LIQUID LOTION LOZENGE POUCH RING SOLUTION SYRUP GRANULE NASAL SPRAY LIP BALM GUMMY LIQUID GEL TRANSDERMAL SYSTEM INTRAUTERINE SYSTEM VAGINAL RING, SLOW RELEASE OTHER
[13]	If Other, please specify:	CMFRMOT	Text or Any Value	4000	
[14]	Total Dose:	CMTOTDOS	Text or Any Value	4000	
[15]	Unit:	CMTOTUN	Categorical select one (nominal)	7	mg mcg mL L ug IU

CEG_P9_153

[16]	If Other, please specify:	CMUNOT	Text or Any Value	4000	g
[17]	Route:	CMROUTE	Categorical select one (nominal)	16	oz gtt Other Unknown
[18]	If other, please specify:	CMOTHER	Text or Any Value	4000	AURICULAR (OTIC) BUCCAL CONJUNCTIVAL CUTANEOUS INTRADERMAL INTRAMUSCULAR INTRAOCULAR INTRASINAL INTRAUTERINE INTRAVENOUS NASAL ORAL RECTAL SUBCUTANEOUS SUBLINGUAL TOPICAL VAGINAL UNKNOWN OTHER
[19]	Frequency:	CMDOSFRQ	Categorical select one (nominal)	16	BID BIM CONTINUOUS EVERY 3 MONTHS EVERY WEEK INTERMITTENT OCCASIONAL ONCE PRN QD QH QID QIS QM QOD TID UNKNOWN 2 TIMES PER WEEK 3 TIMES PER WEEK OTHER
[20]	If Other, please specify:	CMFRQOT	Text or Any Value	4000	
[21]	Start Date:	CMSTDAT	Date	11	
[22]	Start Time:	CMSTTIM	Time	5	
[23]	Time Unknown	CMSTTNK	Categorical yes/no (dichotomous)	3	
[24]	End Date:	CMENDAT	Date	11	
[25]	End Time:	CMEN TIM	Time	5	
[26]	Time Unknown	CMEN TNK	Categorical yes/no (dichotomous)	3	
[27]	Ongoing?	CMONGO	Categorical yes/no (dichotomous)	3	

CEG_P9_153

Use Product Again - VAS at Day 1,Day 2,Day 3,Day 4,Day 5,Day 6

[NOT SUBMITTED]

Was Questionnaire performed? Yes [1]

No

Use: 1st Use [2]

2nd Use

CEG_P9_153

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	

CEG_P9_153

Unscheduled Vital Signs at Unscheduled Visit

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

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_P9_153

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	

CEG_P9_153
Tobacco Use at Screening

SUTRT

SUPPSU.QVAL when QNAM='CIGSTAT'

SUSTDTC

SUENDTC

SU=Substance Use

SUCAT=TOBACCO USE

SUDOSU=ITEM

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 ▾

SUDOSE when SUDOSFRQ='PA'

SUDOSE when SUDOSFRQ='QM'

SUDOSE when SUDOSFRQ='QD'

SUDOSE when SUDOSFRQ='EVERY WEEK'



CEG_P9_153

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	