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Visit Date

Part A - Usual Brand Dose Log

Part A - VLN Dosing Log

Part A - Nicorette Dosing Log

Use Product Again - VAS

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Visit Date

Randomization

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Part B - Controlled Usual Brand Dosing Log

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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

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Visit Date

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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

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Visit Date

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2nd Use - PK Blood Sampling  
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Cotinine Evaluation

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

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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]

1

More rows: 1 5 10

**DSDTC/DSSTDTC**

**SUPPDS.QVAL, when QNAM='ICFVRN'**

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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<br>v2 ICF CEG-P9-153<br>v3 ICF CEG-P9-153 |
| [4] | ICF Version Date:  | DSV DAT     | Date                             | 11         |   |

[NOT SUBMITTED]

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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]

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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         |            |



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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

More rows: 1 5 10

IECAT=EXCLUSION

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

COVAL where COREF='INCLUSION/  
EXCLUSION CRITERIA'

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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<br>INCL02<br>INCL03<br>INCL04<br>INCL05<br>INCL06<br>INCL07<br>INCL08<br>INCL09<br>INCL10<br>INCL11<br>EXCL01<br>EXCL02<br>EXCL03<br>EXCL04<br>EXCL05<br>EXCL06<br>EXCL07<br>EXCL08<br>EXCL09<br>EXCL10<br>EXCL11<br>EXCL12<br>EXCL13<br>EXCL14<br>EXCL15<br>EXCL16<br>EXCL17<br>EXCL18 |
| [4] | Comment:   | IECOM       | Text or Any Value                | 200        |  |

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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

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

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

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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        |            |

MHCAT=GENERAL

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

MHSPID

Medical History #: [3]

1

Date of Visit: [2] MHDTC

MHTERM

Condition: [6]

MHSTDTC

Onset Date: [7]

MHENDTC

Date Resolved: [8]

MHENRF

Ongoing? [9]

☐ Yes ☐ No

SUPPMH.QVAL when QNAM='MHCLSIG'

Safety Review: [10]

☐ Not Clinically  
Sigicant

☐ Clinically  
Significant

Body System Code: [4] If other, please specify: [5]

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'

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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          | HEENT<br>Respiratory<br>Cardiovascular<br>Gastrointestinal<br>Genitourinary/Renal<br>Musculoskeletal<br>Psychiatric/Neurologic<br>Endocrine/Metabolic<br>Hematopoietic/Lymphatic<br>Dermatologic<br>Immunologic/Allergies<br>Oncologic<br>Acute, Chronic, Infectious Disease<br>Hepatic<br>Surgical<br>Other, Specify |
| [2]  | Date of Visit:  | MHDAT       | Date                             | 11         |   |
| [3]  | Medical History #:  | MHNUM       | Number (continuous)              | 15         |   |
| [4]  | Body System Code:   | MHSCAT      | Categorical select one (nominal) | 34         |   |
| [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          | Yes<br>No   |
| [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          |   |
| [12] | Does the subject have a history of recreational drug use?                                   | MHRECUSE    | Categorical yes/no (dichotomous) | 3          |   |

RPCAT=FEMALE CONTRACEPTIVE METHOD

RP=Reproductive System Findings

Visit Date  [1] RPDTC

Childbearing Potential: ☐ CHILDBEARING POTENTIAL [2] RPTTESTCD=CHILDPOT  
☐ NON-CHILDBEARING POTENTIAL

RPTTEST=Childbearing Potential

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

Is subject considered post-menopausal? ☐ Yes [3] RPORRES when RPTTESTCD='MENOSTAT'  
☐ No

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'

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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<br>BIRTH CONTROL PILL<br>CONDOM WITH SPERMICIDE<br>CONDOM WITH DIAPHRAGM<br>CONDOM WITH CONTRACEPTIVE SPONGE<br>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<br>Tubal Ligation<br>Hysterectomy<br>Hysterectomy with bilateral salpingo-oophorectomy<br>Post-menopausal |
| [8] | Procedure Date:   | SCPRODAT    | Date                             | 11         |   |



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

**PESTAT**

**SUPPE.QVAL when QNAM='PETESTOT'**

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10 OTHER ▼

For Annotations see Page 17

☐

- ☐ NORMAL
- ☐ ABNORMAL NCS
- ☐ ABNORMAL CS

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Variable details

|     | Name                                    | Export Name | Type                             | Max length | Categories   |
|-----|---|-------------|----------------------------------|------------|--|
| [1] | Was the physical examination performed? | PEYN        | Categorical yes/no (dichotomous) | 3          | GENERAL APPEARANCE<br>HEENT<br>NECK/THYROID<br>CARDIOVASCULAR<br>RESPIRATORY<br>GASTROINTESTINAL<br>NEUROLOGICAL<br>SKIN<br>OTHER<br>MUSCULOSKELETAL/EXTREMITIES |
| [2] | Examination Date:                       | PEDAT       | Date                             | 11         |  |
| [3] | Completion Time:                        | PETIM       | Time                             | 5          |  |
| [4] | Body System Examined:                   | PETEST      | Categorical select one (nominal) | 27         |  |
| [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        |  |

Visit:  [1] [NOT SUBMITTED]Was the physical examination performed? ☐ Yes ☐ No [2]Examination Date:  [3]Completion Time:  [4]

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

*For Annotations see Page 17*

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10 OTHER ▼

☐

- ☐ ABNORMAL NCS
- ☐ ABNORMAL CS
- ☐ NORMAL
- ☐ ABNORMAL NCS
- ☐ ABNORMAL CS

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Variable details

|     | Name                                    | Export Name | Type                             | Max length | Categories   |
|-----|---|-------------|----------------------------------|------------|--|
| [1] | Visit:                                  | PEVIS       | Categorical select one (nominal) | 17         | Screening<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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<br>HEENT<br>NECK/THYROID<br>CARDIOVASCULAR<br>RESPIRATORY<br>GASTROINTESTINAL<br>NEUROLOGICAL<br>SKIN<br>OTHER<br>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 | <div>General Appearance ▾</div> | <input type="checkbox"/> | <div><input type="radio"/> Normal</div> <div><input type="radio"/> Abnormal NCS</div> <div><input type="radio"/> Abnormal CS</div> | <input type="text"/> |
| 2 | <div>Respiratory ▾</div>        | <input type="checkbox"/> | <div><input type="radio"/> Normal</div> <div><input type="radio"/> Abnormal NCS</div> <div><input type="radio"/> Abnormal CS</div> | <input type="text"/> |
| 3 | <div>Cardiovascular ▾</div>     | <input type="checkbox"/> | <div><input type="radio"/> Normal</div> <div><input type="radio"/> Abnormal NCS</div> <div><input type="radio"/> Abnormal CS</div> | <input type="text"/> |
| 4 | <div>Gastrointestinal ▾</div>   | <input type="checkbox"/> | <div><input type="radio"/> Normal</div> <div><input type="radio"/> Abnormal NCS</div> <div><input type="radio"/> Abnormal CS</div> | <input type="text"/> |
| 5 | <div>Other ▾</div>              | <input type="checkbox"/> | <div><input type="radio"/> Normal</div> <div><input type="radio"/> Abnormal NCS</div> <div><input type="radio"/> Abnormal CS</div> | <input type="text"/> |

If Other, please specify:  [8]

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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<br>Respiratory<br>Cardiovascular<br>Gastrointestinal<br>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

PE=Physical Examination

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 | <input type="checkbox"/> | <input type="radio"/> Normal       | <input type="text"/> |
|   |                    |                          | <input type="radio"/> Abnormal NCS |                      |
|   |                    |                          | <input type="radio"/> Abnormal CS  |                      |
| 2 | Respiratory        | <input type="checkbox"/> | <input type="radio"/> Normal       | <input type="text"/> |
|   |                    |                          | <input type="radio"/> Abnormal NCS |                      |
|   |                    |                          | <input type="radio"/> Abnormal CS  |                      |
| 3 | Cardiovascular     | <input type="checkbox"/> | <input type="radio"/> Normal       | <input type="text"/> |
|   |                    |                          | <input type="radio"/> Abnormal NCS |                      |
|   |                    |                          | <input type="radio"/> Abnormal CS  |                      |
| 4 | Gastrointestinal   | <input type="checkbox"/> | <input type="radio"/> Normal       | <input type="text"/> |
|   |                    |                          | <input type="radio"/> Abnormal NCS |                      |
|   |                    |                          | <input type="radio"/> Abnormal CS  |                      |
| 5 | Other              | <input type="checkbox"/> | <input type="radio"/> Normal       | <input type="text"/> |
|   |                    |                          | <input type="radio"/> Abnormal NCS |                      |
|   |                    |                          | <input type="radio"/> Abnormal CS  |                      |

If Other, please specify: [9]

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Variable details

|     | Name                                | Export Name | Type                             | Max length | Categories   |
|-----|-------------------------------------|-------------|----------------------------------|------------|--|
| [1] | Visit:                              | PEVIS       | Categorical select one (nominal) | 17         | Screening<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>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<br>Respiratory<br>Cardiovascular<br>Gastrointestinal<br>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 [2] 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'

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## 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         |            |

Was the laboratory evaluation performed? ☐ Yes [1] **LBSTAT='NOT DONE' when 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 QNAM='LBCLSIG'**

More rows: 1 5 10

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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<br>HEPATITIS B VIRUS SURFACE ANTIGEN<br>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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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<br>HEPATITIS B VIRUS SURFACE ANTIGEN<br>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:

Time of Collection:

Time Unknown:

[2]

[3]

☐

[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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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:  [2] Time of Collection:  [3] Time Unknown: ☐ [4] **[NOT SUBMITTED]**

# 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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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          |   |



LBCAT=URINE DRUG SCREEN

LB=Laboratory Test Results

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:

[7]

1

☐ NCS

☐ CS

SUPPLB.QVAL when QNAM='LBCLSIG'

More rows: 1 5 10

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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)<br>Opioids<br>Amphetamines<br>Cocaine<br>Benzodiazepines<br>Alcohol<br>Morphine<br>Codeine<br>Heroin<br>Hydrocodone<br>Hydromorphone<br>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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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)<br>Opioids<br>Amphetamines<br>Cocaine<br>Benzodiazepines<br>Alcohol<br>Morphine<br>Codeine<br>Heroin<br>Hydrocodone<br>Hydromorphone<br>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] **LBNRIND**  
☐ No

**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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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'

LBDBC

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<br>Potassium<br>Glucose<br>Creatinine<br>Total Protein<br>Blood Urea Nitrogen (BUN)<br>Albumin<br>Total Bilirubin<br>Alanine Transferase (ALT)<br>Aspartate Transferase (AST)<br>Gamma-Glutamyl Transferase (GGT)<br>Alkaline Phosphatase<br>Creatine Phosphokinase (CK)<br>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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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<br>Potassium<br>Glucose<br>Creatinine<br>Total Protein<br>Blood Urea Nitrogen (BUN)<br>Albumin<br>Total Bilirubin<br>Alanine Transferase (ALT)<br>Aspartate Transferase (AST)<br>Gamma-Glutamyl Transferase (GGT)<br>Alkaline Phosphatase<br>Creatine Phosphokinase (CK)<br>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<br>HEMOGLOBIN<br>RED BLOOD CELL<br>WHITE BLOOD CELL<br>PLATELET COUNT<br>NEUTROPHILS ABSOLUTE<br>NEUTROPHILS<br>LYMPHOCYTES ABSOLUTE<br>LYMPHOCYTES<br>MONOCYTES ABSOLUTE<br>MONOCYTES<br>EOSINOPHILS ABSOLUTE<br>EOSINOPHILS<br>BASOPHILS ABSOLUTE<br>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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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<br>HEMOGLOBIN<br>RED BLOOD CELL<br>WHITE BLOOD CELL<br>PLATELET COUNT<br>NEUTROPHILS ABSOLUTE<br>NEUTROPHILS<br>LYMPHOCYTES ABSOLUTE<br>LYMPHOCYTES<br>MONOCYTES ABSOLUTE<br>MONOCYTES<br>EOSINOPHILS ABSOLUTE<br>EOSINOPHILS<br>BASOPHILS ABSOLUTE<br>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          | Color<br>Nitrite<br>Specific Gravity<br>pH<br>Protein<br>Glucose<br>Ketones<br>Occult Blood<br>Bilirubin<br>Urobilinogen<br>WBC<br>RBC<br>Squamous Epithelial Cells<br>Bacteria<br>Hyaline Cast<br>Crystals |
| [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         |   |
| [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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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<br>Nitrite<br>Specific Gravity<br>pH<br>Protein<br>Glucose<br>Ketones<br>Occult Blood<br>Bilirubin<br>Urobilinogen<br>WBC<br>RBC<br>Squamous Epithelial Cells<br>Bacteria<br>Hyaline Cast<br>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]

☐ No

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

**LBDTC**

Date of collection:

Time of Collection:

Time Unknown:

**[NOT SUBMITTED]**

[2]

[3]

☐ [4]

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 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  FSH (Follicle-Stimulating Hormone) ☐ NCS ☐ CS

CEG\_P9\_153

Variable details

|     | Name  | Export Name | Type                             | Max length | Categories  |
|-----|---|-------------|----------------------------------|------------|---|
| [1] | Visit:  | LBVIS       | Categorical select one (nominal) | 17         | Screening<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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]☐ No

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

Repeat vital signs?

☐ Yes [2]☐ No

[NOT SUBMITTED]

SUPPVS.QVAL when  
QNAM='TIMESPOS'

Time Seated: [3]

Time Seated Unknown: [4]

[NOT SUBMITTED]

Date:

VSDTC

Time Taken:

Time Unknown:

[NOT SUBMITTED]

[5]

[6]

[7]

VSTEST

VSSTAT

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          | Oral Temperature<br>Systolic Blood Pressure<br>Diastolic Blood Pressure<br>Pulse Rate<br>Respirations<br>Heart Rate |
| [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         |   |
|      |                            |             |                                  |            |   |
| [9]  | Not done:                  | VSSTAT      | Categorical yes/no (dichotomous) | 3          | C<br>mmHg<br>beats/min<br>breaths/min   |
| [10] | Result:                    | VSORRES     | Number (continuous)              | 15         |   |
| [11] | Unit:                      | VSORRESU    | Categorical select one (nominal) | 11         |   |
|      |                            |             |                                  |            |   |
| [12] | MD Safety Review:          | VSCLSIG     | Categorical select one (nominal) | 26         |   |

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 <input type="text" value="Oral Temperature"/>         | <input type="checkbox"/> | <input type="text"/> | <input type="text" value="C"/>           | <input type="radio"/> WITHIN NORMAL RANGE<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL NCS<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL CS |
| 2 <input type="text" value="Systolic Blood Pressure"/>  | <input type="checkbox"/> | <input type="text"/> | <input type="text" value="mmHg"/>        | <input type="radio"/> WITHIN NORMAL RANGE<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL NCS<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL CS |
| 3 <input type="text" value="Diastolic Blood Pressure"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text" value="mmHg"/>        | <input type="radio"/> WITHIN NORMAL RANGE<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL NCS<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL CS |
| 4 <input type="text" value="Pulse Rate"/>               | <input type="checkbox"/> | <input type="text"/> | <input type="text" value="beats/min"/>   | <input type="radio"/> WITHIN NORMAL RANGE<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL NCS<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL CS |
| 5 <input type="text" value="Respirations"/>             | <input type="checkbox"/> | <input type="text"/> | <input type="text" value="breaths/min"/> | <input type="radio"/> WITHIN NORMAL RANGE<br><input type="radio"/> OUT-OF-RANGE, ABNORMAL NCS<br><input type="radio"/> 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<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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<br>Systolic Blood Pressure<br>Diastolic Blood Pressure<br>Pulse Rate<br>Respirations<br>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<br>mmHg<br>beats/min<br>breaths/min   |
| [13] | MD Safety Review:          | VSCLSIG     | Categorical select one (nominal) | 26         |   |

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 Q uestionnaire performed at all time points : | Q SPERF     | Categorical yes/no (dichotomous) | 3          |   |
| [2] | Use:  | Q SUSE      | Categorical select one (nominal) | 7          |   |
| [3] | Time point:                                       | Q STMPT     | Categorical select one (nominal) | 9          | Predose<br>5 minute<br>15 minute<br>30 minute<br>60 minute<br>90 minute |
| [4] | Completed:  | Q SYN       | 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 Q uestionnaire performed at all time points : | Q SPERF     | Categorical yes/no (dichotomous) | 3          |   |
| [2] | Use:  | Q SUSE      | Categorical select one (nominal) | 7          |   |
| [3] | Time point:                                       | Q STMPT     | Categorical select one (nominal) | 9          | Predose<br>5 minute<br>15 minute<br>30 minute<br>60 minute<br>90 minute |
| [4] | Completed:  | Q SYN       | Categorical yes/no (dichotomous) | 3          |   |



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 Q uestionnaire performed at all time points : | Q SPERF     | Categorical yes/no (dichotomous) | 3          |   |
| [2] | Use:  | Q SUSE      | Categorical select one (nominal) | 7          |   |
| [3] | Time point:                                       | Q STMPT     | Categorical select one (nominal) | 9          | Predose<br>5 minute<br>15 minute<br>30 minute<br>60 minute<br>90 minute |
| [4] | Completed:  | Q SYN       | 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 Q uestionnaire performed at all time points : | Q SPERF     | Categorical yes/no (dichotomous) | 3          |   |
| [2] | Use:  | Q SUSE      | Categorical select one (nominal) | 7          |   |
| [3] | Time point:                                       | Q STMPT     | Categorical select one (nominal) | 9          | Predose<br>5 minute<br>15 minute<br>30 minute<br>60 minute<br>90 minute |
| [4] | Completed:  | Q SYN       | Categorical yes/no (dichotomous) | 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

EX=Exposure

DA=Drug Accountability

EXTRT=VERY LOW NICOTINE  
CIGARETTES

DASCAT=VERY LOW NICOTINE  
CIGARETTES

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

# 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 - 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'

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          |                                      |

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]

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

EXSTAT=NOT DONE

Time part of EXENDTC

CO=Comments

EX=Exposure

EXTRT=USUAL BRAND  
CIGARETTES

EXGRPID=PART B

EXROUTE=RESPIRATORY  
(INHALATION)

EXLOC=RESPIRATORY SYSTEM

EXCAT=CONTROLLED

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<br>Puff 2<br>Puff 3<br>Puff 4<br>Puff 5<br>Puff 6<br>Puff 7<br>Puff 8<br>Puff 9<br>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          |   |



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]

Session End Time:  [3]

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

1  [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

EX=Exposure

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         |            |

CEG\_P9\_153

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

For Annotations see Page 87

EX=Exposure

EXTRT=VERY LOW NICOTINE  
CIGARETTES

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

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:  | EXPFF       | Categorical select one (nominal) | 7          | Puff 1<br>Puff 2<br>Puff 3<br>Puff 4<br>Puff 5<br>Puff 6<br>Puff 7<br>Puff 8<br>Puff 9<br>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          |   |

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]

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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 Part of EGDTC

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] 

☐ NORMAL

☐ ABNORMAL NCS

☐ ABNORMAL CS

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

COVAL

EGORRES when EGTESTCD='EGVRMN'

EGORRES when EGTESTCD='PRAG'

EGORRES when EGTESTCD='QRSAG'

EGORRES when EGTESTCD='QTAG'

EGORRES when EGTESTCD='QTCBAG'

EGORRES when EGTESTCD='QTCFAG'

EGORRES when EGTESTCD='INTP'

EGEVAL=INVESTIGATOR

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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<br>Day 6<br>Early Term<br>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        |   |



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<br>BCA<br>CAB |

CEG\_P9\_153  
Adverse Events at All Visits

AE=Adverse Events

AESPID

AE Identifier: [2]

Were any Adverse Events experienced?

Yes

No

[1]

Adverse Event Term: [3]

AETERM

Is this an SAE? [4]

Yes

No

Severity: [5]

AESER

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]

Yes

No

AECONTRT

Did the AE result in withdrawal from study? [9]

Yes

No

AERFI

Relationship to Investigational Product: [10]

AEOUT

Was this AE a result of Study Medication error? [11]

Yes

No

SuppAE.QVAL when QNAM='AEDIS'

Outcome: [12]

Date Part of AESTDTC

Onset Date: [13]

TimePart of AESTDTC

Onset Time: [14]

TimePart of AESTDTC

Time Unknown: [15]

SuppAE.QVAL when QNAM='AEMEDERR'

AE Ongoing? [16]

SuppAE.QVAL when QNAM='AEMEDERR'

End Date: [17]

Date Part of AEENDTC

End Time: [18]

Time Part of AEENDTC

Time Unknown: [19]

Time Part of AEENDTC

[NOT SUBMITTED]

[NOT SUBMITTED]

1

More rows: 1 5 10

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Variable details

|      | Name  | Export Name | Type                             | Max length | Categories  |
|------|---|-------------|----------------------------------|------------|---|
| [1]  | Were any Adverse Events experienced?  | AEYN        | Categorical yes/no (dichotomous) | 3          | MILD<br>MODERATE<br>SEVERE  |
| [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          |   |
| [6]  | Frequency:  | AEFREQ      | Categorical select one (nominal) | 14         | Single Episode<br>Intermittent<br>Continuous  |
| [7]  | Action Taken with Study Treatment:  | AEACN       | Categorical select one (nominal) | 24         | No Action Taken<br>Stopped Temporarily<br>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          | Probably Related<br>Possibly Related<br>Unlikely Related<br>Unrelated                             |
| [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         |   |
| [11] | Was this AE a result of Study Medication error?   | AETEA       | Categorical yes/no (dichotomous) | 3          | Resolved<br>Resolved with Sequelae<br>Unresolved/Ongoing<br>Unresolved/Lost to Follow-Up<br>Fatal |
| [12] | Outcome:  | AEOUT       | Categorical select one (nominal) | 28         |   |
| [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:   | AEENTMKN    | Categorical yes/no (dichotomous) | 3          |   |

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: [6] DSTERM when DSDECOD='OTHER'

Additional Comments: [7] COVAL when COREF='END OF STUDY'

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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        |            |

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

**PCSPEC=BLOOD**

Use:

[1]

**[NOT SUBMITTED]**

**PCTPT**

**PCDTC**

Timepoint: [2]

Date: [3]

Time: [4]

Not Done: [5]

Time Unknown [6]

Comments: [7]

**SUPPPC.QVAL when QNAM='PKCODE'**

|   |  |                      |                      |                          |                          |  |
|---|--|----------------------|----------------------|--------------------------|--------------------------|--|
| 1 | <input type="text" value="Predose"/>   | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |
|   |  |                      |                      | <b>PCSTAT</b>            |                          |  |
| 2 | <input type="text" value="2 minute"/>  | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |
| 3 | <input type="text" value="5 minute"/>  | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |
| 4 | <input type="text" value="7 minute"/>  | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |
| 5 | <input type="text" value="10 minute"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |
| 6 | <input type="text" value="12 minute"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |
| 7 | <input type="text" value="15 minute"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |
| 8 | <input type="text" value="20 minute"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> |  |

- ☐ 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

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9 30 minute   ☐ ☐

- ☐ 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

- ☐ 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<br>2 minute<br>5 minute<br>7 minute<br>10 minute<br>12 minute<br>15 minute<br>20 minute<br>30 minute<br>45 minute<br>60 minute<br>90 minute<br>120 minute<br>150 minute<br>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         |   |

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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<br><input type="checkbox"/> B - Late due to previous procedure<br><input type="checkbox"/> C - Early Collection; please specify in Lab Note<br><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<br><input type="checkbox"/> B - Late due to previous procedure<br><input type="checkbox"/> C - Early Collection; please specify in Lab Note<br><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<br><input type="checkbox"/> B - Late due to previous procedure<br><input type="checkbox"/> C - Early Collection; please specify in Lab Note<br><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<br><input type="checkbox"/> B - Late due to previous procedure<br><input type="checkbox"/> C - Early Collection; please specify in Lab Note<br><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<br><input type="checkbox"/> B - Late due to previous procedure<br><input type="checkbox"/> C - Early Collection; please specify in Lab Note<br><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<br><input type="checkbox"/> B - Late due to previous procedure<br><input type="checkbox"/> C - Early Collection; please specify in Lab Note<br><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<br><input type="checkbox"/> B - Late due to previous procedure<br><input type="checkbox"/> C - Early Collection; please specify in Lab Note<br><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   |

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9

30 minute ▾

☐

☐

- ☐ 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

- ☐ 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

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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<br>2 minute<br>5 minute<br>7 minute<br>10 minute<br>12 minute<br>15 minute<br>20 minute<br>30 minute<br>45 minute<br>60 minute<br>90 minute<br>120 minute<br>150 minute<br>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         |   |

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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

CMENDTC

CMENRF

SUPPCM.QVAL when QNAM='CMUNOTH'

SUPPCM.QVAL when QNAM='CMTOTUN'

SUPPCM.QVAL when QNAM='CMFRQOT'

SUPPCM.QVAL when QNAM='CMROUTOT'

SUPPCM.QVAL when QNAM='CMDOFMOT'

SUPPCM.QVAL when QNAM='CMAENO'

SUPPCM.QVAL when QNAM='CMMHNO'

CMDOSTXT

CMDOSTOT

CMDROUTE

CMDOSFRQ

CMSTDTC

CMENDTC

CMENRF

CMDOSU

CMDOSFRM

CMDOSU

CMDOSE

[NOT SUBMITTED]

[NOT SUBMITTED]

if Other Indication then SUPPCM.QVAL when QNAM='CMINDOT'

Linked to related AE record via RELREC

Linked to related MH record via RELREC

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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<br>Adverse Event<br>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<br>mcg<br>mL<br>L<br>ug<br>IU<br>g<br>oz<br>Other<br>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<br>CAPSULE<br>OINTMENT<br>SUPPOSITORY<br>AEROSOL<br>SPRAY<br>SUSPENSION<br>PATCH<br>GEL<br>CREAM<br>POWDER<br>UNKNOWN<br>CAPLET<br>CHEWING<br>IMPLANT<br>INTRAUTERINE DEVICE<br>LIQUID<br>LOTION<br>LOZENGE<br>POUCH<br>RING<br>SOLUTION<br>SYRUP<br>GRANULE<br>NASAL SPRAY<br>LIP BALM<br>GUMMY<br>LIQUID GEL<br>TRANSDERMAL SYSTEM<br>INTRAUTERINE SYSTEM<br>VAGINAL RING, SLOW RELEASE<br>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<br>mcg<br>mL<br>L<br>ug<br>IU  |

|      |                           |          |                                  |      |  |
|------|---------------------------|----------|----------------------------------|------|--|
|      |                           |          |                                  |      | g<br>oz<br>gtt<br>Other<br>Unknown   |
| [16] | If Other, please specify: | CMUNOT   | Text or Any Value                | 4000 |  |
| [17] | Route:                    | CMROUTE  | Categorical select one (nominal) | 16   | AURICULAR (OTIC)<br>BUCCAL<br>CONJUNCTIVAL<br>CUTANEOUS<br>INTRADERMAL<br>INTRAMUSCULAR<br>INTRAOCULAR<br>INTRASINAL<br>INTRAUTERINE<br>INTRAVENOUS<br>NASAL<br>ORAL<br>RECTAL<br>SUBCUTANEOUS<br>SUBLINGUAL<br>TOPICAL<br>VAGINAL<br>UNKNOWN<br>OTHER |
|      |                           |          |                                  |      |  |
| [18] | If other, please specify: | CMOTHER  | Text or Any Value                | 4000 |  |
| [19] | Frequency:                | CMDOSFRQ | Categorical select one (nominal) | 16   | BID<br>BIM<br>CONTINUOUS<br>EVERY 3 MONTHS<br>EVERY WEEK<br>INTERMITTENT<br>OCCASIONAL<br>ONCE<br>PRN<br>QD<br>QH<br>QID<br>QIS<br>QM<br>QOD<br>TID<br>UNKNOWN<br>2 TIMES PER WEEK<br>3 TIMES PER WEEK<br>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:                 | CMENTIM  | Time                             | 5    |  |
| [26] | Time Unknown              | CMENTNK  | Categorical yes/no (dichotomous) | 3    |  |
| [27] | Ongoing?                  | CMONGO   | Categorical yes/no (dichotomous) | 3    |  |

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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



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Variable details

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

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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

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Variable details

|      | Name                       | Export Name | Type                             | Max length | Categories  |
|------|----------------------------|-------------|----------------------------------|------------|---|
| [1]  | Visit:                     | VSVIS       | Categorical select one (nominal) | 17         | Screening<br>Day -1<br>Day 1<br>Day 2<br>Day 3<br>Day 4<br>Day 5<br>Day 6<br>Early Termination<br>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<br>Systolic Blood Pressure<br>Diastolic Blood Pressure<br>Pulse Rate<br>Respirations<br>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<br>mmHg<br>beats/min<br>breaths/min   |
| [12] | MD Safety Review:          | VSCLSIG     | Categorical select one (nominal) | 26         |   |

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='EVERY WEEK'

SUDOSE when  
SUDOSFRQ='QD'

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)<br>Cigar(s)<br>Cigarillo(s)<br>Chewing Tobacco<br>Pipe(s)<br>Nicotine Product(s): (patch, gum, etc)<br>Electronic Cigarette(s)/E-Vapors |
| [2] | Frequency:            | SUFRQ       | Categorical select one (nominal) | 7          | Never<br>Current<br>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         |  |