Table of Contents


01-115 ..... 16

By Visit

- Screening ..... 19
  - Visit Date ..... 19
    - Data ..... 19
    - Audit Trail ..... 19
  - ICF ..... 20
    - Data ..... 20
    - Audit Trail ..... 21
  - INCL/EXCL Criteria Summary ..... 22
    - Data ..... 22
    - Audit Trail ..... 23
  - Demographics ..... 24
    - Data ..... 24
    - Audit Trail ..... 24
  - Medical History ..... 26
    - Data ..... 26
    - Audit Trail ..... 28
  - Complete Physical Examination ..... 30
    - Data ..... 30
    - Audit Trail ..... 33
  - Height, Weight and BMI ..... 36
    - Data ..... 36
    - Audit Trail ..... 36
  - Serology Lab Evaluation ..... 37
    - Data ..... 37
    - Audit Trail ..... 38
  - Serum Pregnancy Test ..... 39
    - Data ..... 39
  - Vital Signs ..... 40
    - Data ..... 40
    - Audit Trail ..... 43
  - UDS and Alcohol Laboratory Evaluation ..... 45
    - Data ..... 45
    - Audit Trail ..... 46
  - Cotinine Evaluation ..... 47
    - Data ..... 47
    - Audit Trail ..... 48
  - Chemistry Laboratory Evaluation ..... 49
    - Data ..... 49
    - Audit Trail ..... 50
  - Hematology Laboratory Evaluation ..... 51
    - Data ..... 51

Audit Trail ..... 52
Urinalysis Laboratory Evaluation ..... 53
Data ..... 53
Audit Trail ..... 54
Endocrinology Evaluation ..... 55
Data ..... 55
ECG Test Results ..... 56
Data ..... 56
Audit Trail ..... 57
Female Contraceptive Method ..... 59
Data ..... 59
Tobacco Use ..... 60
Data ..... 60
Audit Trail ..... 64
Query Log ..... 65
Day -1 ..... 67
Visit Date ..... 67
Data ..... 67
Audit Trail ..... 67
Urine Pregnancy Test ..... 69
Data ..... 69
Vital Signs ..... 69
Data ..... 69
Audit Trail ..... 72
UDS and Alcohol Laboratory Evaluation ..... 74
Data ..... 74
Audit Trail ..... 75
Symptom Directed Physical Exam ..... 76
Data ..... 76
Audit Trail ..... 77
Day 1 ..... 78
Visit Date ..... 78
Data ..... 78
Audit Trail ..... 78
Part A - Usual Brand Dose Log ..... 79
Data ..... 79
Part A - VLN Dosing Log ..... 80
Data ..... 80
Part A - Nicorette Dosing Log ..... 81
Data ..... 81
Audit Trail ..... 82
Randomization ..... 84
Data ..... 84

Audit Trail ..... 84
Use Product Again - VAS ..... 86
Data ..... 86
Audit Trail ..... 86
Day 2 ..... 87
Visit Date ..... 87
Data ..... 87
Audit Trail ..... 88
Part A - Usual Brand Dose Log ..... 89
Data ..... 89
Part A - VLN Dosing Log ..... 90
Data ..... 90
Audit Trail ..... 91
Part A - Nicorette Dosing Log ..... 94
Data ..... 94
Use Product Again - VAS ..... 95
Data ..... 95
Audit Trail ..... 95
Day 3 ..... 96
Visit Date ..... 96
Data ..... 96
Audit Trail ..... 97
Part A - Usual Brand Dose Log ..... 98
Data ..... 98
Audit Trail ..... 100
Part A - VLN Dosing Log ..... 102
Data ..... 102
Part A - Nicorette Dosing Log ..... 103
Data ..... 103
Use Product Again - VAS ..... 104
Data ..... 104
Audit Trail ..... 105
Day 4 ..... 106
Visit Date ..... 106
Data ..... 106
Audit Trail ..... 106
Randomization ..... 107
Data ..... 107
Audit Trail ..... 108
Part B - Controlled Nicorette Dosing Log-1 ..... 109
Data ..... 109
Part B - Uncontrolled Nicorette Dosing Log ..... 110
Data ..... 110

Table of Contents


Part B - Uncontrolled Usual Brand Dosing Log ..... 111
Data ..... 111
Audit Trail ..... 117
Part B - Controlled Usual Brand Dosing Log ..... 120
Data ..... 120
Audit Trail ..... 124
Part B - Controlled VLN Dosing Log ..... 127
Data ..... 127
Part B - Uncontrolled VLN Dosing Log ..... 129
Data ..... 129
1st Use - Tobacco/Nicotine Questionnaire ..... 130
Data ..... 130
Audit Trail ..... 130
2nd Use - Tobacco/Nicotine Questionnaire ..... 132
Data ..... 132
Audit Trail ..... 132
1st Use - Direct Effects of Product Questionnaire ..... 133
Data ..... 133
Audit Trail ..... 134
2nd Use - Direct Effects of Product Questionnaire ..... 135
Data ..... 135
Audit Trail ..... 135
1st Use - PK Blood Sampling ..... 136
Data ..... 136
Audit Trail ..... 142
2nd Use - PK Blood Sampling ..... 146
Data ..... 146
Audit Trail ..... 152
Use Product Again - VAS 1st use ..... 155
Data ..... 155
Audit Trail ..... 156
Use Product Again - VAS 2nd use ..... 157
Data ..... 157
Audit Trail ..... 157
Day 5 ..... 158
Visit Date ..... 158
Data ..... 158
Audit Trail ..... 159
Part B - Controlled Nicorette Dosing Log ..... 160
Data ..... 160
Audit Trail ..... 160
Part B - Uncontrolled Nicorette Dosing Log ..... 162
Data ..... 162

Table of Contents


Audit Trail ..... 162
Part B - Uncontrolled Usual Brand Dosing Log ..... 164
Data ..... 164
Part B - Controlled Usual Brand Dosing Log ..... 165
Data ..... 165
Part B - Controlled VLN Dosing Log ..... 167
Data ..... 167
Part B - Uncontrolled VLN Dosing Log ..... 168
Data ..... 168
1st Use - Tobacco/Nicotine Questionnaire ..... 169
Data ..... 169
Audit Trail ..... 170
2nd Use - Tobacco/Nicotine Questionnaire ..... 171
Data ..... 171
Audit Trail ..... 171
1st Use - Direct Effects of Product Questionnaire ..... 172
Data ..... 172
Audit Trail ..... 173
2nd Use - Direct Effects of Product Questionnaire ..... 174
Data ..... 174
Audit Trail ..... 175
1st Use - PK Blood Sampling ..... 176
Data ..... 176
Audit Trail ..... 182
2nd Use - PK Blood Sampling ..... 185
Data ..... 185
Audit Trail ..... 191
Use Product Again - VAS 1st use ..... 194
Data ..... 194
Audit Trail ..... 195
Use Product Again - VAS 2nd use ..... 196
Data ..... 196
Audit Trail ..... 196
Day 6 ..... 197
Visit Date ..... 197
Data ..... 197
Audit Trail ..... 198
Vital Signs ..... 199
Data ..... 199
Audit Trail ..... 201
Chemistry Laboratory Evaluation ..... 203
Data ..... 203
Audit Trail ..... 204

Table of Contents


Hematology Laboratory Evaluation ..... 205
Data ..... 205
Audit Trail ..... 206
Urinalysis Laboratory Evaluation ..... 207
Data ..... 207
Audit Trail ..... 208
Symptom Directed Physical Exam ..... 209
Data ..... 209
Audit Trail ..... 210
Part B - Controlled Nicorette Dosing Log-1 ..... 211
Data ..... 211
Part B - Uncontrolled Nicorette Dosing Log ..... 212
Data ..... 212
Part B - Controlled Usual Brand Dosing Log ..... 213
Data ..... 213
Part B - Uncontrolled Usual Brand Dosing Log ..... 215
Data ..... 215
Part B - Controlled VLN Dosing Log ..... 216
Data ..... 216
Audit Trail ..... 220
Query Log ..... 223
Part B - Uncontrolled VLN Dosing Log ..... 224
Data ..... 224
Audit Trail ..... 226
ECG Test Results ..... 228
Data ..... 228
Audit Trail ..... 230
1st Use - Tobacco/Nicotine Questionnaire ..... 231
Data ..... 231
Audit Trail ..... 232
2nd Use - Tobacco/Nicotine Questionnaire ..... 233
Data ..... 233
Audit Trail ..... 233
1st Use - Direct Effects of Product Questionnaire ..... 235
Data ..... 235
Audit Trail ..... 235
2nd Use - Direct Effects of Product Questionnaire ..... 236
Data ..... 236
Audit Trail ..... 237
End of Study ..... 238
Data ..... 238
Audit Trail ..... 238
1st Use - PK Blood Sampling ..... 240

Data ..... 240
Audit Trail ..... 246
Query Log ..... 250
2nd Use - PK Blood Sampling ..... 252
Data ..... 252
Audit Trail ..... 258
Use Product Again - VAS 1st use ..... 261
Data ..... 261
Audit Trail ..... 261
Use Product Again - VAS 2nd use ..... 262
Data ..... 262
Audit Trail ..... 263
Early Term ..... 264
Visit Date ..... 264
Data ..... 264
Vital Signs ..... 265
Data ..... 265
Chemistry Laboratory Evaluation ..... 266
Data ..... 266
Hematology Laboratory Evaluation ..... 267
Data ..... 267
Urinalysis Laboratory Evaluation ..... 268
Data ..... 268
Symptom Directed Physical Exam ..... 269
Data ..... 269
ECG Test Results ..... 271
Data ..... 271
End of Study ..... 272
Data ..... 272
1st Use - PK Blood Sampling ..... 273
Data ..... 273
2nd Use - PK Blood Sampling ..... 274
Data ..... 274
All Visits ..... 275
Adverse Events ..... 275
Data ..... 275
Audit Trail ..... 277
Concomitant Medications ..... 278
Data ..... 278
Audit Trail ..... 280

By Domain

Visit Date ..... 19
Screening ..... 19

Data ..... 19
Audit Trail ..... 19
Day -1 ..... 67
Data ..... 67
Audit Trail ..... 67
Day 1 ..... 78
Data ..... 78
Audit Trail ..... 78
Day 2 ..... 87
Data ..... 87
Audit Trail ..... 88
Day 3 ..... 96
Data ..... 96
Audit Trail ..... 97
Day 4 ..... 106
Data ..... 106
Audit Trail ..... 106
Day 5 ..... 158
Data ..... 158
Audit Trail ..... 159
Day 6 ..... 197
Data ..... 197
Audit Trail ..... 198
Early Term ..... 264
Data ..... 264
ICF ..... 20
Screening ..... 19
Data ..... 20
Audit Trail ..... 21
INCL/EXCL Criteria Summary ..... 22
Screening ..... 19
Data ..... 22
Audit Trail ..... 23
Demographics ..... 24
Screening ..... 19
Data ..... 24
Audit Trail ..... 24
Medical History ..... 26
Screening ..... 19
Data ..... 26
Audit Trail ..... 28
Complete Physical Examination ..... 30
Screening ..... 19

Data ..... 30
Audit Trail ..... 33
Height, Weight and BMI ..... 36
Screening ..... 19
Data ..... 36
Audit Trail ..... 36
Serology Lab Evaluation ..... 37
Screening ..... 19
Data ..... 37
Audit Trail ..... 38
Serum Pregnancy Test ..... 39
Screening ..... 19
Data ..... 39
Vital Signs ..... 40
Screening ..... 19
Data ..... 40
Audit Trail ..... 43
Day -1 ..... 67
Data ..... 69
Audit Trail ..... 72
Day 6 ..... 197
Data ..... 199
Audit Trail ..... 201
Early Term ..... 264
Data ..... 265
UDS and Alcohol Laboratory Evaluation ..... 45
Screening ..... 19
Data ..... 45
Audit Trail ..... 46
Day -1 ..... 67
Data ..... 74
Audit Trail ..... 75
Cotinine Evaluation ..... 47
Screening ..... 19
Data ..... 47
Audit Trail ..... 48
Chemistry Laboratory Evaluation ..... 49
Screening ..... 19
Data ..... 49
Audit Trail ..... 50
Day 6 ..... 197
Data ..... 203
Audit Trail ..... 204

Early Term ..... 264
Data ..... 266
Hematology Laboratory Evaluation ..... 51
Screening ..... 19
Data ..... 51
Audit Trail ..... 52
Day 6 ..... 197
Data ..... 205
Audit Trail ..... 206
Early Term ..... 264
Data ..... 267
Urinalysis Laboratory Evaluation ..... 53
Screening ..... 19
Data ..... 53
Audit Trail ..... 54
Day 6 ..... 197
Data ..... 207
Audit Trail ..... 208
Early Term ..... 264
Data ..... 268
Endocrinology Evaluation ..... 55
Screening ..... 19
Data ..... 55
ECG Test Results ..... 56
Screening ..... 19
Data ..... 56
Audit Trail ..... 57
Day 6 ..... 197
Data ..... 228
Audit Trail ..... 230
Early Term ..... 264
Data ..... 271
Female Contraceptive Method ..... 59
Screening ..... 19
Data ..... 59
Tobacco Use ..... 60
Screening ..... 19
Data ..... 60
Audit Trail ..... 64
Query Log ..... 65
Urine Pregnancy Test ..... 69
Day -1 ..... 67
Data ..... 69

Table of Contents


Symptom Directed Physical Exam ..... 76
Day -1 ..... 67
Data ..... 76
Audit Trail ..... 77
Day 6 ..... 197
Data ..... 209
Audit Trail ..... 210
Early Term ..... 264
Data ..... 269
Part A - Usual Brand Dose Log ..... 79
Day 1 ..... 78
Data ..... 79
Day 2 ..... 87
Data ..... 89
Day 3 ..... 96
Data ..... 98
Audit Trail ..... 100
Part A - VLN Dosing Log ..... 80
Day 1 ..... 78
Data ..... 80
Day 2 ..... 87
Data ..... 90
Audit Trail ..... 91
Day 3 ..... 96
Data ..... 102
Part A - Nicorette Dosing Log ..... 81
Day 1 ..... 78
Data ..... 81
Audit Trail ..... 82
Day 2 ..... 87
Data ..... 94
Day 3 ..... 96
Data ..... 103
Randomization ..... 84
Day 1 ..... 78
Data ..... 84
Audit Trail ..... 84
Day 4 ..... 106
Data ..... 107
Audit Trail ..... 108
Use Product Again - VAS ..... 86
Day 1 ..... 78
Data ..... 86

Audit Trail ..... 86
Day 2 ..... 87
Data ..... 95
Audit Trail ..... 95
Day 3 ..... 96
Data ..... 104
Audit Trail ..... 105
Part B - Controlled Nicorette Dosing Log-1 ..... 109
Day 4 ..... 106
Data ..... 109
Day 6 ..... 197
Data ..... 211
Part B - Uncontrolled Nicorette Dosing Log ..... 110
Day 4 ..... 106
Data ..... 110
Day 5 ..... 158
Data ..... 162
Audit Trail ..... 162
Day 6 ..... 197
Data ..... 212
Part B - Uncontrolled Usual Brand Dosing Log ..... 111
Day 4 ..... 106
Data ..... 111
Audit Trail ..... 117
Day 5 ..... 158
Data ..... 164
Day 6 ..... 197
Data ..... 215
Part B - Controlled Usual Brand Dosing Log ..... 120
Day 4 ..... 106
Data ..... 120
Audit Trail ..... 124
Day 5 ..... 158
Data ..... 165
Day 6 ..... 197
Data ..... 213
Part B - Controlled VLN Dosing Log ..... 127
Day 4 ..... 106
Data ..... 127
Day 5 ..... 158
Data ..... 167
Day 6 ..... 197
Data ..... 216

Audit Trail ..... 220
Query Log ..... 223
Part B - Uncontrolled VLN Dosing Log ..... 129
Day 4 ..... 106
Data ..... 129
Day 5 ..... 158
Data ..... 168
Day 6 ..... 197
Data ..... 224
Audit Trail ..... 226
1st Use - Tobacco/Nicotine Questionnaire ..... 130
Day 4 ..... 106
Data ..... 130
Audit Trail ..... 130
Day 5 ..... 158
Data ..... 169
Audit Trail ..... 170
Day 6 ..... 197
Data ..... 231
Audit Trail ..... 232
2nd Use - Tobacco/Nicotine Questionnaire ..... 132
Day 4 ..... 106
Data ..... 132
Audit Trail ..... 132
Day 5 ..... 158
Data ..... 171
Audit Trail ..... 171
Day 6 ..... 197
Data ..... 233
Audit Trail ..... 233
1st Use - Direct Effects of Product Questionnaire ..... 133
Day 4 ..... 106
Data ..... 133
Audit Trail ..... 134
Day 5 ..... 158
Data ..... 172
Audit Trail ..... 173
Day 6 ..... 197
Data ..... 235
Audit Trail ..... 235
2nd Use - Direct Effects of Product Questionnaire ..... 135
Day 4 ..... 106
Data ..... 135

Audit Trail ..... 135
Day 5 ..... 158
Data ..... 174
Audit Trail ..... 175
Day 6 ..... 197
Data ..... 236
Audit Trail ..... 237
1st Use - PK Blood Sampling ..... 136
Day 4 ..... 106
Data ..... 136
Audit Trail ..... 142
Day 5 ..... 158
Data ..... 176
Audit Trail ..... 182
Day 6 ..... 197
Data ..... 240
Audit Trail ..... 246
Query Log ..... 250
Early Term ..... 264
Data ..... 273
2nd Use - PK Blood Sampling ..... 146
Day 4 ..... 106
Data ..... 146
Audit Trail ..... 152
Day 5 ..... 158
Data ..... 185
Audit Trail ..... 191
Day 6 ..... 197
Data ..... 252
Audit Trail ..... 258
Early Term ..... 264
Data ..... 274
Use Product Again - VAS 1st use ..... 155
Day 4 ..... 106
Data ..... 155
Audit Trail ..... 156
Day 5 ..... 158
Data ..... 194
Audit Trail ..... 195
Day 6 ..... 197
Data ..... 261
Audit Trail ..... 261
Use Product Again - VAS 2nd use ..... 157

Day 4 ..... 106
Data ..... 157
Audit Trail ..... 157
Day 5 ..... 158
Data ..... 196
Audit Trail ..... 196
Day 6 ..... 197
Data ..... 262
Audit Trail ..... 263
Part B - Controlled Nicorette Dosing Log ..... 160
Day 5 ..... 158
Data ..... 160
Audit Trail ..... 160
End of Study ..... 238
Day 6 ..... 197
Data ..... 238
Audit Trail ..... 238
Early Term ..... 264
Data ..... 272
Adverse Events ..... 275
All Visits ..... 275
Data ..... 275
Audit Trail ..... 277
Concomitant Medications ..... 278
All Visits ..... 275
Data ..... 278
Audit Trail ..... 280

| | |
|---|---|
| Site: | Site A |
| Group: | Group A |
| Medrio ID: | 0036 |
| Subject Identifier: | 01-115 |
| Status: | Completed |
| Timezone: | Pacific Standard Time |
| Study Name: | CEG-P9-153 |

## SUBJECT INFORMATION HISTORY

| Object | Date Time | User | Old Value | New Value |
|---|---|---|---|---|
| Subject Status | 03-Jul-2018 10:34 AM PDT (UTC-07:00) | (b) (6) vinceandassociates.com ((b) (6) | Enrolled | Completed |
| Subject ID | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | (b) (6) vinceandassociates.com ((b) (6) | | 01-115 |
| Medrio ID | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | (b) (6) vinceandassociates.com ((b) (6) | | 36 |
| Subject Status | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | (b) (6) vinceandassociates.com ((b) (6) | | Enrolled |
| Site | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | (b) (6) vinceandassociates.com ((b) (6) | | Site A |
| Group | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | (b) (6) vinceandassociates.com ((b) (6) | | Group A |
| ePRO Enabled | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | (b) (6) vinceandassociates.com ((b) (6) | | No |

## SUBJECT LOCKING HISTORY

| Locked | Date/Time | User |
|---|---|---|
| Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com ((b) (6) (b) (6) |

## VISIT LOCKING HISTORY

| Visit | Locked | Date/Time | User |
|---|---|---|---|
| Screening | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com ((b) (6) (b) (6) |
| Day -1 | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com ((b) (6) (b) (6) |
| Day 1 | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com ((b) (6) (b) (6) |
| Day 2 | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com ((b) (6) (b) (6) |
| Day 3 | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com ((b) (6) (b) (6) |

| Visit | Locked | Date/Time | User |
|---|---|---|---|
| Day 4 | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com (b) (6) (b) (6) |
| Day 5 | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com (b) (6) (b) (6) |
| Day 6 | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com (b) (6) (b) (6) |
| Early Term | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com (b) (6) (b) (6) |
| All Visits | Locked | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | (b) (6) algopharm.com (b) (6) (b) (6) |

## CLINICAL DATA

VISIT: Screening
FORM: Visit Date

| | |
|---|---|
| Visit Done?<br>[SVYN] | Yes |
| Date of Visit:<br>[SVSTDAT] | 11-Jun-2018 |

## AUDIT TRAIL

VISIT: Screening
FORM: Visit Date

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:16 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN<br>[SVYN] | | Yes |
| SVSTDAT<br>[SVSTDAT] | | 11-Jun-2018 |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Visit Date

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:16 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Visit Date

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |

| User | Date/Time | Status |
|---|---|---|
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 01-Aug-2018 02:48 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Screening
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Screening
FORM: ICF

| | |
|---|---|
| Was the most current IRB approved version of the Informed Consent signed by the subject? [DSYN] | Yes |
| | |
| Row 1 | |
| Date Subject Signed ICF: (Original signature) [DSDAT] | 11-Jun-2018 |
| ICF Version: [DSVERS] | v3 ICF CEG-P9-153 |
| ICF Version Date: [DSVDAT] | 01-May-2018 |

## AUDIT TRAIL

VISIT: Screening
FORM: ICF

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:16 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| DSYN [DSYN] | | Yes |
| [Row 1] DSDATE [DSDAT] | | 11-Jun-2018 |
| [Row 1] DSVERS [DSVERS] | | v3 ICF CEG-P9-153 |
| [Row 1] DSVDAT [DSVDAT] | | 01-May-2018 |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: ICF

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:16 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: ICF

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com (b) (6) (b) (6) | 01-Aug-2018 02:17 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: ICF

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

| | |
|---|---|
| Does the subject meet all eligibility criteria required by the protocol? [IEYN] | Yes |
| If NO, please specify the inclusion and/or exclusion criteria number: | |

| Row 1 | |
|---|---|
| Specify: [IECAT] | |
| Number: [IETESTCD] | |
| Comment: [IECOM] | |

## AUDIT TRAIL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:17 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| IEYN<br>[IEYN] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:17 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Demographics

| | |
|---|---|
| Visit Date: [DMDAT] | 11-Jun-2018 |
| Date of Birth: [DMBRTHDAT] | (b) (6) |
| Age: [DMAGE] | 29 |
| Age Unit: [DMAGEU] | YEARS |
| Gender: [DMSEX] | M |
| Ethnicity: [DMETHNIC] | NOT HISPANIC OR LATINO |
| Race: [DMRACE] | WHITE |
| Other, Specify: [DMRCOT] | |

## AUDIT TRAIL

VISIT: Screening
FORM: Demographics

| | |
|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) (b) (6) |
| **Date/Time** | 16-Aug-2018 01:57 PM PDT (UTC-07:00) |

| | | |
|---|---|---|
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Reason for change:** | Data entry error | |
| **Variable** | **Old Value** | **New Value** |
| DMETHNIC [DMETHNIC] | HISPANIC OR LATINO | NOT HISPANIC OR LATINO |
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) (b) (6) | |
| **Date/Time** | 05-Jul-2018 02:17 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Reason for change:** | Data entry error | |
| **Variable** | **Old Value** | **New Value** |
| DMBRTHDAT [DMBRTHDAT] | 05-May-1989 | 10-May-1989 |
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 25-Jun-2018 08:18 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| DMDAT [DMDAT] | | 11-Jun-2018 |
| DMBRTHDAT [DMBRTHDAT] | | (b) (6) |
| DMAGE [DMAGE] | | 29 |
| DMAGEU [DMAGEU] | | YEARS |
| DMSEX [DMSEX] | | M |
| DMETHNIC [DMETHNIC] | | HISPANIC OR LATINO |
| DMRACE [DMRACE] | | WHITE |

**FORM STATUS CHANGE LOG**

VISIT: Screening
FORM: Demographics

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:18 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Demographics

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 19-Sep-2018 02:28 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |
| (b) (6) vinceandassociates.com ((b) (6) (b) (6) | 16-Aug-2018 01:57 PM PDT (UTC-07:00) | Data entry error ( Form partially unmarked as "Form Monitored" ).(DMETHNIC) |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Demographics

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Medical History

| | |
|---|---|
| Does the subject have any relevant medical or surgical history (including drug allergies)? [MHYN] | Yes |

| | |
|---|---|
| Date of Visit:<br>[MHDAT] | 11-Jun-2018 |
| Row 1 | |
| Medical History #:<br>[MHNUM] | 1 |
| Body System Code:<br>[MHSCAT] | Gastrointestinal |
| If other, please specify:<br>[MHOTHSP] | |
| Condition:<br>[MHSCAT] | APPENDICITIS |
| Onset Date:<br>[MHSTDAT] | UN-UNK-2004 |
| Date Resolved:<br>[MHENDAT] | UN-UNK-2004 |
| Ongoing?<br>[MHONGO] | |
| Safety Review:<br>[MHCLSIG] | Not Clinically Sigficant |
| Row 2 | |
| Medical History #:<br>[MHNUM] | 2 |
| Body System Code:<br>[MHSCAT] | Surgical |
| If other, please specify:<br>[MHOTHSP] | |
| Condition:<br>[MHSCAT] | APPENDECTOMY |
| Onset Date:<br>[MHSTDAT] | UN-UNK-2004 |
| Date Resolved:<br>[MHENDAT] | UN-UNK-2004 |
| Ongoing?<br>[MHONGO] | |

| | |
|---|---|
| Safety Review:<br>[MHCLSIG] | Not Clinically Sigficant |

| | |
|---|---|
| Does the subject self-report the desire to smoke within approximately 30 minutes of waking?<br>[MHSMK] | Yes |
| Does the subject have a history of recreational drug use?<br>[MHRECUSE] | No |

**AUDIT TRAIL**

VISIT: Screening
FORM: Medical History

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 25-Jun-2018 08:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| MHYN<br>[MHYN] | | Yes |
| MHDAT<br>[MHDAT] | | 11-Jun-2018 |
| [Row 1] MHNUM<br>[MHNUM] | | 1 |
| [Row 1] MHSCAT<br>[MHSCAT] | | Gastrointestinal |
| [Row 1] MHCAT<br>[MHSCAT] | | APPENDICITIS |
| [Row 1] MHSTDAT<br>[MHSTDAT] | | UN-UNK-2004 |
| [Row 1] MHENDAT<br>[MHENDAT] | | UN-UNK-2004 |
| [Row 1] MHCLSIG<br>[MHCLSIG] | | Not Clinically Sigficant |
| [Row 2] MHNUM<br>[MHNUM] | | 2 |
| [Row 2] MHSCAT<br>[MHSCAT] | | Surgical |
| [Row 2] MHCAT<br>[MHSCAT] | | APPENDECTOMY |
| [Row 2] MHSTDAT | | UN-UNK-2004 |

| Variable | Old Value | New Value |
|---|---|---|
| [MHSTDAT] | | |
| [Row 2] MHENDAT [MHENDAT] | | UN-UNK-2004 |
| [Row 2] MHCLSIG [MHCLSIG] | | Not Clinically Sigficant |
| MHSMK [MHSMK] | | Yes |
| MHRECUSE [MHRECUSE] | | No |

**FORM STATUS CHANGE LOG**

VISIT: Screening
FORM: Medical History

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Screening
FORM: Medical History

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Medical History

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Complete Physical Examination

| | |
|---|---|
| Was the physical examination performed? [PEYN] | Yes |
| Examination Date: [PEDAT] | 11-Jun-2018 |
| Completion Time: [PETIM] | 14:50 |
| Row 1 | |
| Body System Examined: [PETEST] | GENERAL APPEARANCE |
| Not done: [PESTAT] | |
| If Other, please specify: [PEOTHSP] | |
| Examination Result: [PEORRES] | NORMAL |
| Abnormal Findings: [PEDESC] | |
| Row 2 | |
| Body System Examined: [PETEST] | HEENT |
| Not done: [PESTAT] | |

| | |
|---|---|
| If Other, please specify:<br>[PEOTHSP] | |
| Examination Result:<br>[PEORRES] | NORMAL |
| Abnormal Findings:<br>[PEDESC] | |
| Row 3 | |
| Body System Examined:<br>[PETEST] | NECK/THYROID |
| Not done:<br>[PESTAT] | |
| If Other, please specify:<br>[PEOTHSP] | |
| Examination Result:<br>[PEORRES] | NORMAL |
| Abnormal Findings:<br>[PEDESC] | |
| Row 4 | |
| Body System Examined:<br>[PETEST] | CARDIOVASCULAR |
| Not done:<br>[PESTAT] | |
| If Other, please specify:<br>[PEOTHSP] | |
| Examination Result:<br>[PEORRES] | NORMAL |
| Abnormal Findings:<br>[PEDESC] | |
| Row 5 | |
| Body System Examined:<br>[PETEST] | RESPIRATORY |
| Not done:<br>[PESTAT] | |
| If Other, please specify:<br>[PEOTHSP] | |

| | |
|---|---|
| Examination Result: [PEORRES] | NORMAL |
| Abnormal Findings: [PEDESC] | |
| Row 6 | |
| Body System Examined: [PETEST] | GASTROINTESTINAL |
| Not done: [PESTAT] | |
| If Other, please specify: [PEOTHSP] | |
| Examination Result: [PEORRES] | NORMAL |
| Abnormal Findings: [PEDESC] | |
| Row 7 | |
| Body System Examined: [PETEST] | NEUROLOGICAL |
| Not done: [PESTAT] | |
| If Other, please specify: [PEOTHSP] | |
| Examination Result: [PEORRES] | NORMAL |
| Abnormal Findings: [PEDESC] | |
| Row 8 | |
| Body System Examined: [PETEST] | MUSCULOSKELETAL/EXTREMITIES |
| Not done: [PESTAT] | |
| If Other, please specify: [PEOTHSP] | |
| Examination Result: [PEORRES] | NORMAL |

| | |
|---|---|
| Abnormal Findings: [PEDESC] | |
| Row 9 | |
| Body System Examined: [PETEST] | SKIN |
| Not done: [PESTAT] | |
| If Other, please specify: [PEOTHSP] | |
| Examination Result: [PEORRES] | NORMAL |
| Abnormal Findings: [PEDESC] | |
| Row 10 | |
| Body System Examined: [PETEST] | OTHER |
| Not done: [PESTAT] | Yes |
| If Other, please specify: [PEOTHSP] | |
| Examination Result: [PEORRES] | |
| Abnormal Findings: [PEDESC] | |

**AUDIT TRAIL**

VISIT: Screening
FORM: Complete Physical Examination

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 25-Jun-2018 08:31 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PEYN [PEYN] | | Yes |

| Variable | Old Value | New Value |
|---|---|---|
| PEDAT<br>[PEDAT] | | 11-Jun-2018 |
| PETIM<br>[PETIM] | | 14:50 |
| [Row 1] PETEST<br>[PETEST] | | GENERAL APPEARANCE |
| [Row 1] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 2] PETEST<br>[PETEST] | | HEENT |
| [Row 2] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 3] PETEST<br>[PETEST] | | NECK/THYROID |
| [Row 3] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 4] PETEST<br>[PETEST] | | CARDIOVASCULAR |
| [Row 4] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 5] PETEST<br>[PETEST] | | RESPIRATORY |
| [Row 5] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 6] PETEST<br>[PETEST] | | GASTROINTESTINAL |
| [Row 6] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 7] PETEST<br>[PETEST] | | NEUROLOGICAL |
| [Row 7] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 8] PETEST<br>[PETEST] | | MUSCULOSKELETAL/EXTREMITIES |
| [Row 8] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 9] PETEST<br>[PETEST] | | SKIN |
| [Row 9] PEORRES<br>[PEORRES] | | NORMAL |
| [Row 10] PETEST<br>[PETEST] | | OTHER |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 10] PESTAT [PESTAT] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Complete Physical Examination

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:31 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Complete Physical Examination

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Complete Physical Examination

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Height, Weight and BMI

| | |
|---|---|
| Was the assessment performed?<br>[VSYN] | Yes |
| Visit Date:<br>[VSDAT] | 11-Jun-2018 |
| Height:<br>[VSHGT] | 174.0 |
| Weight:<br>[VSWGT] | 72.1 |
| BMI:<br>[VSBMI] | 23.8 |

## AUDIT TRAIL

VISIT: Screening
FORM: Height, Weight and BMI

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 25-Jun-2018 08:19 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| VSYN<br>[VSYN] | | Yes |
| VSDAT<br>[VSDAT] | | 11-Jun-2018 |
| VSHGT<br>[VSHGT] | | 174.0 |
| VSWGT<br>[VSWGT] | | 72.1 |
| VSBMI<br>[VSBMI] | | 23.8 |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Height, Weight and BMI

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:19 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Height, Weight and BMI

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Height, Weight and BMI

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Serology Lab Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |

| | |
|---|---|
| Date of collection:<br>[LBDAT] | 11-Jun-2018 |
| Time of Collection:<br>[LBTIM] | 14:57 |
| Time Unknown:<br>[LBTMNK] | |
| Are all results within normal limits?<br>[LBNRIND] | Yes |

| Row 1 | |
|---|---|
| Test Name:<br>[LBTEST] | |
| Clinical Significance as per MD: (Please record an AE for Clinically Significant results)<br>[LBCLSIG] | |

**AUDIT TRAIL**

VISIT: Screening
FORM: Serology Lab Evaluation

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:22 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN<br>[LBYN] | | Yes |
| LBDAT<br>[LBDAT] | | 11-Jun-2018 |
| LBTIM<br>[LBTIM] | | 14:57 |
| LBNRIND<br>[LBNRIND] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serology Lab Evaluation

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:22 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Serology Lab Evaluation

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Serology Lab Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Serum Pregnancy Test

| | |
|---|---|
| Was Serum Pregnancy Test performed? [LBHCGYN] | |

| | |
|---|---|
| Date of collection:<br>[LBDAT] | |
| Time of Collection:<br>[LBTIM] | |
| Time Unknown:<br>[LBTMNK] | |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serum Pregnancy Test

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Screening
FORM: Serum Pregnancy Test

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Vital Signs

| | |
|---|---|
| Were vital signs measured?<br>[VSPERF] | Yes |
| Repeat vital signs?<br>[VSPERFR] | No |
| Time Seated:<br>[VS1TIMS] | 14:29 |
| Time Seated Unknown:<br>[VSTIMSUN] | |
| Date:<br>[VSDAT] | 11-Jun-2018 |

| | |
|---|---|
| Time Taken:<br>[VSTIM] | 14:34 |
| Time Unknown:<br>[VSTMNK] | |
| Row 1 | |
| Assessment:<br>[VSTEST] | Oral Temperature |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 36.6 |
| Unit:<br>[VSORRESU] | C |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 2 | |
| Assessment:<br>[VSTEST] | Systolic Blood Pressure |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 119 |
| Unit:<br>[VSORRESU] | mmHg |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 3 | |
| Assessment:<br>[VSTEST] | Diastolic Blood Pressure |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 81 |

| | |
|---|---|
| Unit:<br>[VSORRESU] | mmHg |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 4 | |
| Assessment:<br>[VSTEST] | Pulse Rate |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 66 |
| Unit:<br>[VSORRESU] | beats/min |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 5 | |
| Assessment:<br>[VSTEST] | Respirations |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 12 |
| Unit:<br>[VSORRESU] | breaths/min |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |

**AUDIT TRAIL**

VISIT: Screening
FORM: Vital Signs

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:21 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| VSPERF [VSPERF] | | Yes |
| VSPERFR [VSPERFR] | | No |
| VSTIMS [VS1TIMS] | | 14:29 |
| VS1DAT [VSDAT] | | 11-Jun-2018 |
| VSTIM [VSTIM] | | 14:34 |
| [Row 1] VSTEST [VSTEST] | | Oral Temperature |
| [Row 1] VSORRES [VSORRES] | | 36.6 |
| [Row 1] VSORRESU [VSORRESU] | | C |
| [Row 1] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 2] VSTEST [VSTEST] | | Systolic Blood Pressure |
| [Row 2] VSORRES [VSORRES] | | 119 |
| [Row 2] VSORRESU [VSORRESU] | | mmHg |
| [Row 2] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 3] VSTEST [VSTEST] | | Diastolic Blood Pressure |
| [Row 3] VSORRES [VSORRES] | | 81 |
| [Row 3] VSORRESU [VSORRESU] | | mmHg |
| [Row 3] VSCLSIG | | WITHIN NORMAL RANGE |

| Variable | Old Value | New Value |
|---|---|---|
| [VSCLSIG] | | |
| [Row 4] VSTEST [VSTEST] | | Pulse Rate |
| [Row 4] VSORRES [VSORRES] | | 66 |
| [Row 4] VSORRESU [VSORRESU] | | beats/min |
| [Row 4] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 5] VSTEST [VSTEST] | | Respirations |
| [Row 5] VSORRES [VSORRES] | | 12 |
| [Row 5] VSORRESU [VSORRESU] | | breaths/min |
| [Row 5] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |

**FORM STATUS CHANGE LOG**

VISIT: Screening
FORM: Vital Signs

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:21 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Screening
FORM: Vital Signs

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Vital Signs

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 11-Jun-2018 |
| Time of Collection: [LBTIM] | 15:05 |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | Yes |

| Row 1 | |
|---|---|
| Test Name: [LBTEST] | |
| Clinical Significance as per MD: [LBCLSIG] | |

## AUDIT TRAIL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:23 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN1 [LBYN] | | Yes |
| LBDAT3 [LBDAT] | | 11-Jun-2018 |
| LBTIM3 [LBTIM] | | 15:05 |
| LBNRIND3 [LBNRIND] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:23 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Cotinine Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 11-Jun-2018 |
| Time of Collection: [LBTIM] | 15:05 |
| Time Unknown: [LBTMNK] | |
| Is the result within range? [LBNRIND] | No |
| Row 1 | |
| Test Name: [LBTEST] | Cotinine |
| Clinical Significance as per MD: [LBCLSIG] | NCS |

## AUDIT TRAIL

VISIT: Screening
FORM: Cotinine Evaluation

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:24 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN4<br>[LBYN] | | Yes |
| LBDAT4<br>[LBDAT] | | 11-Jun-2018 |
| LBTIM4<br>[LBTIM] | | 15:05 |
| LBNRIND4<br>[LBNRIND] | | No |
| [Row 1] LBTEST5<br>[LBTEST] | | Cotinine |
| [Row 1] LBCLSIG4<br>[LBCLSIG] | | NCS |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Cotinine Evaluation

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:24 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Cotinine Evaluation

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |

| User | Date/Time | Status |
|---|---|---|
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Cotinine Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 11-Jun-2018 |
| Time of Collection: [LBTIM] | 14:57 |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | Yes |
| Row 1 | |
| Test Name: [LBTEST] | |

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

## AUDIT TRAIL

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:22 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN2 [LBYN] | | Yes |
| LBDAT5 [LBDAT] | | 11-Jun-2018 |
| LBTIM5 [LBTIM] | | 14:57 |
| LBNRIND5 [LBNRIND] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:22 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |

| User | Date/Time | Status |
|---|---|---|
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Hematology Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 11-Jun-2018 |
| Time of Collection: [LBTIM] | 14:57 |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | Yes |
| Row 1 | |
| Test Name: [LBTEST] | |

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

## AUDIT TRAIL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:23 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN6 [LBYN] | | Yes |
| LBDAT6 [LBDAT] | | 11-Jun-2018 |
| LBTIM6 [LBTIM] | | 14:57 |
| LBNRIND6 [LBNRIND] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Hematology Laboratory Evaluation

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:23 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |

| User | Date/Time | Status |
|---|---|---|
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Screening
FORM: Hematology Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 11-Jun-2018 |
| Time of Collection: [LBTIM] | 15:05 |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | Yes |
| Row 1 | |
| Test Name: [LBTEST] | |

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

## AUDIT TRAIL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:24 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN3 [LBYN] | | Yes |
| LBDAT7 [LBDAT] | | 11-Jun-2018 |
| LBTIM7 [LBTIM] | | 15:05 |
| LBNRIND7 [LBNRIND] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:24 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |

| User | Date/Time | Status |
|---|---|---|
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Endocrinology Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | |
| Date of collection: [LBDAT] | |
| Time of Collection: [LBTIM] | |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | |
| Row 1 | |
| Test Name: [LBTEST] | |

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

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Endocrinology Evaluation

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Screening
FORM: Endocrinology Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: ECG Test Results

| | |
|---|---|
| Was the ECG performed? [EGYN] | Yes |
| Date: [EGDAT] | 11-Jun-2018 |
| Visit: [EGVIS] | Screening |
| Row 1 | |
| Time: [EGTIM] | 14:28 |
| Time Unknown: [EGTMNK] | |

| | |
|---|---|
| Position:<br>[EGPOS] | SUPINE |
| VR:<br>[EGVR] | 62 |
| PR Interval:<br>[EGPR] | 178 |
| QRS Interval:<br>[EGQRS] | 92 |
| QT Interval:<br>[EGQT] | 411 |
| QTcB Interval:<br>[EGQTCB] | 418 |
| QTcF:<br>[EGQTCF] | 415 |
| Clinical Significance as per MD:<br>[EGCLSIG] | NORMAL |
| If Abnormal and Clinically Significant, please specify abnormalities:<br>[EGCOM] | |

**AUDIT TRAIL**

VISIT: Screening
FORM: ECG Test Results

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:20 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EG1YN<br>[EGYN] | | Yes |
| EG1DAT<br>[EGDAT] | | 11-Jun-2018 |
| EGVIS<br>[EGVIS] | | Screening |
| [Row 1] EG1TIM<br>[EGTIM] | | 14:28 |
| [Row 1] EG1POS | | SUPINE |

| Variable | Old Value | New Value |
|---|---|---|
| [EGPOS] | | |
| [Row 1] EGVR [EGVR] | | 62 |
| [Row 1] EG1PR [EGPR] | | 178 |
| [Row 1] EG1QRS [EGQRS] | | 92 |
| [Row 1] EG1QT [EGQT] | | 411 |
| [Row 1] EGQTCB [EGQTCB] | | 418 |
| [Row 1] EG1QTCF [EGQTCF] | | 415 |
| [Row 1] EG1CLSIG [EGCLSIG] | | NORMAL |

**FORM STATUS CHANGE LOG**

VISIT: Screening
FORM: ECG Test Results

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:20 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Screening
FORM: ECG Test Results

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Screening
FORM: ECG Test Results

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Female Contraceptive Method

| | |
|---|---|
| Visit Date [SCDAT] | |
| Childbearing Potential: [SCSTATUS] | |
| Is subject considered post-menopausal? [SCPOST] | |
| Last menses: [SCMENDAT] | |

| Row 1 | |
|---|---|
| Please select the contraceptive method used by subject: [SCTEST] | |
| Start Date: [SCSTDAT] | |

| Row 1 | |
|---|---|
| Females of non-childbearing potential must meet at least one of the following criteria: [SCSUR] | |
| Procedure Date: [SCPRODAT] | |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Female Contraceptive Method

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Screening
FORM: Female Contraceptive Method

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Screening
FORM: Tobacco Use

| Row 1 | |
|---|---|
| Type of tobacco used? [SUTRT] | Cigarette(s) |
| Frequency: [SUFRQ] | Current |
| Start Date: [SUSTDAT] | UN-UNK-2007 |
| End Date: [SUENDAT] | |
| Yearly Use: [SUYRUS] | |
| Monthly Use: [SUMONUS] | |
| Weekly Use: [SUWKUS] | |

| | |
|---|---|
| Daily Use:<br>[SUDYUS] | 15 |
| Row 2 | |
| Type of tobacco used?<br>[SUTRT] | Cigar(s) |
| Frequency:<br>[SUFRQ] | Never |
| Start Date:<br>[SUSTDAT] | |
| End Date:<br>[SUENDAT] | |
| Yearly Use:<br>[SUYRUS] | |
| Monthly Use:<br>[SUMONUS] | |
| Weekly Use:<br>[SUWKUS] | |
| Daily Use:<br>[SUDYUS] | |
| Row 3 | |
| Type of tobacco used?<br>[SUTRT] | Cigarillo(s) |
| Frequency:<br>[SUFRQ] | Never |
| Start Date:<br>[SUSTDAT] | |
| End Date:<br>[SUENDAT] | |
| Yearly Use:<br>[SUYRUS] | |
| Monthly Use:<br>[SUMONUS] | |
| Weekly Use:<br>[SUWKUS] | |

| | |
|---|---|
| Daily Use:<br>[SUDYUS] | |
| Row 4 | |
| Type of tobacco used?<br>[SUTRT] | Chewing Tobacco |
| Frequency:<br>[SUFRQ] | Never |
| Start Date:<br>[SUSTDAT] | |
| End Date:<br>[SUENDAT] | |
| Yearly Use:<br>[SUYRUS] | |
| Monthly Use:<br>[SUMONUS] | |
| Weekly Use:<br>[SUWKUS] | |
| Daily Use:<br>[SUDYUS] | |
| Row 5 | |
| Type of tobacco used?<br>[SUTRT] | Pipe(s) |
| Frequency:<br>[SUFRQ] | Never |
| Start Date:<br>[SUSTDAT] | |
| End Date:<br>[SUENDAT] | |
| Yearly Use:<br>[SUYRUS] | |
| Monthly Use:<br>[SUMONUS] | |
| Weekly Use:<br>[SUWKUS] | |

| | |
|---|---|
| Daily Use:<br>[SUDYUS] | |
| Row 6 | |
| Type of tobacco used?<br>[SUTRT] | Nicotine Product(s): (patch, gum, etc) |
| Frequency:<br>[SUFRQ] | Never |
| Start Date:<br>[SUSTDAT] | |
| End Date:<br>[SUENDAT] | |
| Yearly Use:<br>[SUYRUS] | |
| Monthly Use:<br>[SUMONUS] | |
| Weekly Use:<br>[SUWKUS] | |
| Daily Use:<br>[SUDYUS] | |
| Row 7 | |
| Type of tobacco used?<br>[SUTRT] | Electronic Cigarette(s)/E-Vapors |
| Frequency:<br>[SUFRQ] | Never |
| Start Date:<br>[SUSTDAT] | |
| End Date:<br>[SUENDAT] | |
| Yearly Use:<br>[SUYRUS] | |
| Monthly Use:<br>[SUMONUS] | |
| Weekly Use:<br>[SUWKUS] | |

| | |
|---|---|
| Daily Use:<br>[SUDYUS] | |

**AUDIT TRAIL**

VISIT: Screening
FORM: Tobacco Use

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6) | |
|---|---|---|
| **Date/Time** | 11-Jul-2018 11:15 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| [Row 1] SUTRT1<br>[SUTRT] | | Cigarette(s) |
| [Row 1] SUFRQ1<br>[SUFRQ] | | Current |
| [Row 1] SUSTDAT1<br>[SUSTDAT] | | UN-UNK-2007 |
| [Row 1] SUDYUS1<br>[SUDYUS] | | 15 |
| [Row 2] SUTRT1<br>[SUTRT] | | Cigar(s) |
| [Row 2] SUFRQ1<br>[SUFRQ] | | Never |
| [Row 3] SUTRT1<br>[SUTRT] | | Cigarillo(s) |
| [Row 3] SUFRQ1<br>[SUFRQ] | | Never |
| [Row 4] SUTRT1<br>[SUTRT] | | Chewing Tobacco |
| [Row 4] SUFRQ1<br>[SUFRQ] | | Never |
| [Row 5] SUTRT1<br>[SUTRT] | | Pipe(s) |
| [Row 5] SUFRQ1<br>[SUFRQ] | | Never |
| [Row 6] SUTRT1<br>[SUTRT] | | Nicotine Product(s): (patch, gum, etc) |
| [Row 6] SUFRQ1<br>[SUFRQ] | | Never |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 7] SUTRT1 [SUTRT] | | Electronic Cigarette(s)/E-Vapors |
| [Row 7] SUFRQ1 [SUFRQ] | | Never |

## FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Tobacco Use

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 16-Jul-2018 09:27 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 11-Jul-2018 11:15 AM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 11-Jul-2018 11:15 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 09-Jul-2018 08:40 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Screening
FORM: Tobacco Use

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## QUERIES

VISIT: Screening
FORM: Tobacco Use

| ID | Variable | Responses/Reasons | Opened | Closed |
|---|---|---|---|---|
| | [Row 1] SUYRUS1 | NOT APPLICABLE [11-Jul-2018 11:19 AM | 11-Jul-2018 11:15 AM | 16-Jul-2018 09:21 AM |

| ID | Variable | Responses/Reasons | Opened | Closed |
|---|---|---|---|---|
| | | by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) Response satisfies query [16-Jul-2018 09:21 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) | | |
| | **Description** | | | |
| | **New:** Yearly Use is missing, please review<br>**Old:**<br>**By:** 11-Jul-2018 11:15 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) | | | |
| | [Row 1] SUWKUS1 | NOT APPLICABLE [11-Jul-2018 11:19 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) Response satisfies query [16-Jul-2018 09:21 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) | 11-Jul-2018 11:15 AM | 16-Jul-2018 09:21 AM |
| | **Description** | | | |
| | **New:** Weekly Use is missing, please review<br>**Old:**<br>**By:** 11-Jul-2018 11:15 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) | | | |
| | [Row 1] SUMONUS1 | NOT APPLICABLE [11-Jul-2018 11:19 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) Response satisfies query [16-Jul-2018 09:27 AM | 11-Jul-2018 11:15 AM | 16-Jul-2018 09:27 AM |

| ID | Variable | Responses/Reasons | Opened | Closed |
|---|---|---|---|---|
| | | by (b) (6) vinceandassociates.com ((b) (6) (b) (6) | | |
| | **Description** | | | |
| | **New:** Monthly Use is missing, please review<br>**Old:**<br>**By:** 11-Jul-2018 11:15 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) | | | |

## LOCKING HISTORY

VISIT: Screening
FORM: Tobacco Use

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day -1
FORM: Visit Date

| | |
|---|---|
| Visit Done?<br>[SVYN] | Yes |
| Date of Visit:<br>[SVSTDAT] | 22-Jun-2018 |

## AUDIT TRAIL

VISIT: Day -1
FORM: Visit Date

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 25-Jun-2018 08:32 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN<br>[SVYN] | | Yes |
| SVSTDAT | | 22-Jun-2018 |

| Variable | Old Value | New Value |
|---|---|---|
| [SVSTDAT] | | |

## FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Visit Date

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:32 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day -1
FORM: Visit Date

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day -1
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day -1
FORM: Urine Pregnancy Test

| | |
|---|---|
| Was Urine Pregnancy Test performed?<br>[LBHCGYN] | |
| Date of collection:<br>[LBDAT] | |
| Time of Collection:<br>[LBTIM] | |
| Time Unknown:<br>[LBTMNK] | |

## FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Urine Pregnancy Test

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day -1
FORM: Urine Pregnancy Test

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day -1
FORM: Vital Signs

| | |
|---|---|
| Were vital signs measured?<br>[VSPERF] | Yes |
| Repeat vital signs?<br>[VSPERFR] | No |

| | |
|---|---|
| Time Seated:<br>[VS1TIMS] | 07:58 |
| Time Seated Unknown:<br>[VSTIMSUN] | |
| Date:<br>[VSDAT] | 22-Jun-2018 |
| Time Taken:<br>[VSTIM] | 08:03 |
| Time Unknown:<br>[VSTMNK] | |

| Row 1 | |
|---|---|
| Assessment:<br>[VSTEST] | Oral Temperature |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 36.8 |
| Unit:<br>[VSORRESU] | C |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 2 | |
| Assessment:<br>[VSTEST] | Systolic Blood Pressure |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 129 |
| Unit:<br>[VSORRESU] | mmHg |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |

| | |
|---|---|
| Row 3 | |
| Assessment:<br>[VSTEST] | Diastolic Blood Pressure |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 89 |
| Unit:<br>[VSORRESU] | mmHg |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 4 | |
| Assessment:<br>[VSTEST] | Pulse Rate |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 73 |
| Unit:<br>[VSORRESU] | beats/min |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 5 | |
| Assessment:<br>[VSTEST] | Respirations |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 10 |
| Unit:<br>[VSORRESU] | breaths/min |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |

**AUDIT TRAIL**

VISIT: Day -1
FORM: Vital Signs

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:33 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| VSPERF [VSPERF] | | Yes |
| VSPERFR [VSPERFR] | | No |
| VSTIMS [VS1TIMS] | | 07:58 |
| VS1DAT [VSDAT] | | 22-Jun-2018 |
| VSTIM [VSTIM] | | 08:03 |
| [Row 1] VSTEST [VSTEST] | | Oral Temperature |
| [Row 1] VSORRES [VSORRES] | | 36.8 |
| [Row 1] VSORRESU [VSORRESU] | | C |
| [Row 1] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 2] VSTEST [VSTEST] | | Systolic Blood Pressure |
| [Row 2] VSORRES [VSORRES] | | 129 |
| [Row 2] VSORRESU [VSORRESU] | | mmHg |
| [Row 2] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 3] VSTEST [VSTEST] | | Diastolic Blood Pressure |
| [Row 3] VSORRES [VSORRES] | | 89 |
| [Row 3] VSORRESU [VSORRESU] | | mmHg |
| [Row 3] VSCLSIG | | WITHIN NORMAL RANGE |

| Variable | Old Value | New Value |
|---|---|---|
| [VSCLSIG] | | |
| [Row 4] VSTEST [VSTEST] | | Pulse Rate |
| [Row 4] VSORRES [VSORRES] | | 73 |
| [Row 4] VSORRESU [VSORRESU] | | beats/min |
| [Row 4] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 5] VSTEST [VSTEST] | | Respirations |
| [Row 5] VSORRES [VSORRES] | | 10 |
| [Row 5] VSORRESU [VSORRESU] | | breaths/min |
| [Row 5] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |

**FORM STATUS CHANGE LOG**

VISIT: Day -1
FORM: Vital Signs

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:33 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day -1
FORM: Vital Signs

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day -1
FORM: Vital Signs

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day -1
FORM: UDS and Alcohol Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 22-Jun-2018 |
| Time of Collection: [LBTIM] | 07:47 |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | Yes |

| Row 1 | |
|---|---|
| Test Name: [LBTEST] | |
| Clinical Significance as per MD: [LBCLSIG] | |

## AUDIT TRAIL

VISIT: Day -1
FORM: UDS and Alcohol Laboratory Evaluation

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:32 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN1 [LBYN] | | Yes |
| LBDAT3 [LBDAT] | | 22-Jun-2018 |
| LBTIM3 [LBTIM] | | 07:47 |
| LBNRIND3 [LBNRIND] | | Yes |

## FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: UDS and Alcohol Laboratory Evaluation

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:32 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day -1
FORM: UDS and Alcohol Laboratory Evaluation

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day -1
FORM: UDS and Alcohol Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day -1
FORM: Symptom Directed Physical Exam

| | |
|---|---|
| Was physical examination performed? [PEYN] | No |
| Examination Date: [PEDAT] | |
| Completion Time: [PTIM] | |
| ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM | |
| Row 1 | |
| Body System Examined: [PETEST] | |
| Not done: [PESTAT] | |
| Examination Results: [PEORRES] | |
| Abnormal Findings: [PECLSIG] | |
| | |
| If Other, please specify: [PEOTHSP] | |

## AUDIT TRAIL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:33 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PEYN2<br>[PEYN] | | No |

## FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Symptom Directed Physical Exam

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:33 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day -1
FORM: Symptom Directed Physical Exam

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 1
FORM: Visit Date

| | |
|---|---|
| Visit Done? [SVYN] | Yes |
| Date of Visit: [SVSTDAT] | 23-Jun-2018 |

## AUDIT TRAIL

VISIT: Day 1
FORM: Visit Date

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 25-Jun-2018 08:34 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN [SVYN] | | Yes |
| SVSTDAT [SVSTDAT] | | 23-Jun-2018 |

## FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Visit Date

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:34 AM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 1
FORM: Visit Date

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Day 1
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 1
FORM: Part A - Usual Brand Dose Log

| | |
|---|---|
| AD LIB USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG | |
| Date of Visit: [EXDAT] | |
| Row 1 | |
| Product Used: [EXPRDT] | |

| | |
|---|---|
| Number Dispensed:<br>[EXDSPD] | |
| Time Dispensed:<br>[EXTIM] | |
| Number of Butts Returned:<br>[EXCIGRET] | |
| Time Returned:<br>[EXTIMRET] | |

## FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Part A - Usual Brand Dose Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 1
FORM: Part A - Usual Brand Dose Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 1
FORM: Part A - VLN Dosing Log

| | |
|---|---|
| AD LIB VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG | |
| Date of Visit:<br>[EXDAT] | |

| Row 1 | |
|---|---|
| Product Used:<br>[EXPRDT] | |
| Number Dispensed:<br>[EXDSPD] | |
| Time Dispensed:<br>[EXTIM] | |
| Number of Butts Returned:<br>[EXCIGRET] | |
| Time Returned:<br>[EXTIMRET] | |

## FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Part A - VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 1
FORM: Part A - VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 1
FORM: Part A - Nicorette Dosing Log

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

| | |
|---|---|
| Date of Visit:<br>[EXDAT] | 23-Jun-2018 |
| Row 1 | |
| Product Used:<br>[EXPRDT] | Nicorette Original Flavor Gum (4 mg) |
| Number Dispensed:<br>[EXDSPD] | 1 |
| Time Dispensed:<br>[EXTIM] | 10:00 |
| Number of Pieces Returned:<br>[EXNICRET] | 1 |
| Time Returned/Discarded:<br>[EXTIMRET] | 10:04 |
| Row 2 | |
| Product Used:<br>[EXPRDT] | Nicorette Original Flavor Gum (4 mg) |
| Number Dispensed:<br>[EXDSPD] | 1 |
| Time Dispensed:<br>[EXTIM] | 13:14 |
| Number of Pieces Returned:<br>[EXNICRET] | 1 |
| Time Returned/Discarded:<br>[EXTIMRET] | 13:24 |

**AUDIT TRAIL**

VISIT: Day 1
FORM: Part A - Nicorette Dosing Log

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 26-Jun-2018 08:36 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EXDAT2 | | 23-Jun-2018 |

| Variable | Old Value | New Value |
|---|---|---|
| [EXDAT] | | |
| [Row 1] EXPRDT2 [EXPRDT] | | Nicorette Original Flavor Gum (4 mg) |
| [Row 1] EXDSPD2 [EXDSPD] | | 1 |
| [Row 1] EXTIM2 [EXTIM] | | 10:00 |
| [Row 1] EXNICRET [EXNICRET] | | 1 |
| [Row 1] EXTIMRET2 [EXTIMRET] | | 10:04 |
| [Row 2] EXPRDT2 [EXPRDT] | | Nicorette Original Flavor Gum (4 mg) |
| [Row 2] EXDSPD2 [EXDSPD] | | 1 |
| [Row 2] EXTIM2 [EXTIM] | | 13:14 |
| [Row 2] EXNICRET [EXNICRET] | | 1 |
| [Row 2] EXTIMRET2 [EXTIMRET] | | 13:24 |

**FORM STATUS CHANGE LOG**

VISIT: Day 1
FORM: Part A - Nicorette Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 26-Jun-2018 08:36 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:48 AM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 1
FORM: Part A - Nicorette Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 02-Aug-2018 09:10 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 1
FORM: Part A - Nicorette Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 1
FORM: Randomization

| | |
|---|---|
| Date of Randomization: [DSRDAT] | 23-Jun-2018 |
| Randomization Number: [DSNUM] | 1041 |
| Sequence Group [DSRNGRP] | CAB |

## AUDIT TRAIL

VISIT: Day 1
FORM: Randomization

| | |
|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) |
| **Date/Time** | 25-Jun-2018 08:48 AM PDT (UTC-07:00) |

| | | |
|---|---|---|
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Reason for change:** | Updated information | |
| **Variable** | **Old Value** | **New Value** |
| DSRNGRP [DSRNGRP] | | CAB |
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 25-Jun-2018 08:34 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| DSRNDAT [DSRDAT] | | 23-Jun-2018 |
| DSRNUM [DSNUM] | | 1041 |

**FORM STATUS CHANGE LOG**

VISIT: Day 1
FORM: Randomization

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:48 AM PDT (UTC-07:00) | Form marked as Complete |
| (b) (6) vinceandassociates.com ((b) (6) | 25-Jun-2018 08:34 AM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:34 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 1
FORM: Randomization

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |

| User | Date/Time | Status |
|---|---|---|
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 1
FORM: Randomization

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 1
FORM: Use Product Again - VAS

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |
| Use: [QSUSE] | 1st Use |

## AUDIT TRAIL

VISIT: Day 1
FORM: Use Product Again - VAS

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:35 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF [QSPERF] | | Yes |
| QS5USE [QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Use Product Again - VAS

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:35 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 1
FORM: Use Product Again - VAS

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 1
FORM: Use Product Again - VAS

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 2
FORM: Visit Date

| | |
|---|---|
| Visit Done? [SVYN] | Yes |

| | |
|---|---|
| Date of Visit:<br>[SVSTDAT] | 24-Jun-2018 |

## AUDIT TRAIL

VISIT: Day 2
FORM: Visit Date

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:35 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN<br>[SVYN] | | Yes |
| SVSTDAT<br>[SVSTDAT] | | 24-Jun-2018 |

## FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Visit Date

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:35 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 2
FORM: Visit Date

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 2
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 2
FORM: Part A - Usual Brand Dose Log

| | |
|---|---|
| AD LIB USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG | |
| Date of Visit: [EXDAT] | |
| Row 1 | |
| Product Used: [EXPRDT] | |
| Number Dispensed: [EXDSPD] | |
| Time Dispensed: [EXTIM] | |
| Number of Butts Returned: [EXCIGRET] | |
| Time Returned: [EXTIMRET] | |

## FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Part A - Usual Brand Dose Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 2
FORM: Part A - Usual Brand Dose Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 2
FORM: Part A - VLN Dosing Log

| | |
|---|---|
| AD LIB VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG | |
| Date of Visit: [EXDAT] | 24-Jun-2018 |
| Row 1 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 10:00 |
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 10:05 |
| Row 2 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |

| | |
|---|---|
| Time Dispensed: [EXTIM] | 11:10 |
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 11:17 |
| Row 3 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 12:30 |
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 12:36 |
| Row 4 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 13:38 |
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 13:46 |

**AUDIT TRAIL**

VISIT: Day 2
FORM: Part A - VLN Dosing Log

| | |
|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) |
| **Date/Time** | 26-Jun-2018 09:18 AM PDT (UTC-07:00) |

| **Application Used** | Web Browser (EDC) | |
|---|---|---|
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EXDAT1<br>[EXDAT] | | 24-Jun-2018 |
| [Row 1] EXPRDT1<br>[EXPRDT] | | Combustible Cigarette |
| [Row 1] EXDSPD1<br>[EXDSPD] | | 1 |
| [Row 1] EXTIM1<br>[EXTIM] | | 10:00 |
| [Row 1] EXCIGRET1<br>[EXCIGRET] | | 1 |
| [Row 1] EXTIMRET1<br>[EXTIMRET] | | 10:05 |
| [Row 2] EXPRDT1<br>[EXPRDT] | | Combustible Cigarette |
| [Row 2] EXDSPD1<br>[EXDSPD] | | 1 |
| [Row 2] EXTIM1<br>[EXTIM] | | 11:10 |
| [Row 2] EXCIGRET1<br>[EXCIGRET] | | 1 |
| [Row 2] EXTIMRET1<br>[EXTIMRET] | | 11:17 |
| [Row 3] EXPRDT1<br>[EXPRDT] | | Combustible Cigarette |
| [Row 3] EXDSPD1<br>[EXDSPD] | | 1 |
| [Row 3] EXTIM1<br>[EXTIM] | | 12:30 |
| [Row 3] EXCIGRET1<br>[EXCIGRET] | | 1 |
| [Row 3] EXTIMRET1<br>[EXTIMRET] | | 12:36 |
| [Row 4] EXPRDT1<br>[EXPRDT] | | Combustible Cigarette |
| [Row 4] EXDSPD1<br>[EXDSPD] | | 1 |
| [Row 4] EXTIM1<br>[EXTIM] | | 13:38 |
| [Row 4] EXCIGRET1<br>[EXCIGRET] | | 1 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 4] EXTIMRET1 [EXTIMRET] | | 13:46 |

## FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Part A - VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 26-Jun-2018 09:18 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:48 AM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 2
FORM: Part A - VLN Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 02-Aug-2018 09:10 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 2
FORM: Part A - VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| | | | (b) (6) (b) (6) | | | |

## CLINICAL DATA

VISIT: Day 2
FORM: Part A - Nicorette Dosing Log

| | |
|---|---|
| AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG | |
| Date of Visit: [EXDAT] | |
| Row 1 | |
| Product Used: [EXPRDT] | |
| Number Dispensed: [EXDSPD] | |
| Time Dispensed: [EXTIM] | |
| Number of Pieces Returned: [EXNICRET] | |
| Time Returned/Discarded: [EXTIMRET] | |

## FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Part A - Nicorette Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 2
FORM: Part A - Nicorette Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 2
FORM: Use Product Again - VAS

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |
| Use: [QSUSE] | 1st Use |

## AUDIT TRAIL

VISIT: Day 2
FORM: Use Product Again - VAS

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 25-Jun-2018 08:35 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF [QSPERF] | | Yes |
| QS5USE [QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Use Product Again - VAS

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 25-Jun-2018 08:35 AM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 2
FORM: Use Product Again - VAS

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Day 2
FORM: Use Product Again - VAS

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 3
FORM: Visit Date

| | |
|---|---|
| Visit Done? [SVYN] | Yes |
| Date of Visit: [SVSTDAT] | 25-Jun-2018 |

## AUDIT TRAIL

VISIT: Day 3
FORM: Visit Date

| Logged in User | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| Date/Time | 26-Jun-2018 08:26 AM PDT (UTC-07:00) | |
| Application Used | Web Browser (EDC) | |
| Subject Entry | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN [SVYN] | | Yes |
| SVSTDAT [SVSTDAT] | | 25-Jun-2018 |

## FORM STATUS CHANGE LOG

VISIT: Day 3
FORM: Visit Date

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 26-Jun-2018 08:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 3
FORM: Visit Date

| User | Date/Time | Status |
|---|---|---|
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 3
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 3
FORM: Part A - Usual Brand Dose Log

| | |
|---|---|
| AD LIB USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG | |
| Date of Visit: [EXDAT] | 25-Jun-2018 |
| Row 1 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 10:00 |
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 10:09 |
| Row 2 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 10:45 |

| | |
|---|---|
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 10:54 |
| Row 3 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 11:43 |
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 11:53 |
| Row 4 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 12:41 |
| Number of Butts Returned: [EXCIGRET] | 1 |
| Time Returned: [EXTIMRET] | 12:49 |
| Row 5 | |
| Product Used: [EXPRDT] | Combustible Cigarette |
| Number Dispensed: [EXDSPD] | 1 |
| Time Dispensed: [EXTIM] | 13:40 |
| Number of Butts Returned: [EXCIGRET] | 1 |

| | |
|---|---|
| Time Returned: [EXTIMRET] | 13:49 |

**AUDIT TRAIL**

VISIT: Day 3
FORM: Part A - Usual Brand Dose Log

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 26-Jun-2018 09:27 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EXDAT [EXDAT] | | 25-Jun-2018 |
| [Row 1] EXPRDT [EXPRDT] | | Combustible Cigarette |
| [Row 1] EXDSPD [EXDSPD] | | 1 |
| [Row 1] EXTIM [EXTIM] | | 10:00 |
| [Row 1] EXCIGRET [EXCIGRET] | | 1 |
| [Row 1] EXTIMRET [EXTIMRET] | | 10:09 |
| [Row 2] EXPRDT [EXPRDT] | | Combustible Cigarette |
| [Row 2] EXDSPD [EXDSPD] | | 1 |
| [Row 2] EXTIM [EXTIM] | | 10:45 |
| [Row 2] EXCIGRET [EXCIGRET] | | 1 |
| [Row 2] EXTIMRET [EXTIMRET] | | 10:54 |
| [Row 3] EXPRDT [EXPRDT] | | Combustible Cigarette |
| [Row 3] EXDSPD [EXDSPD] | | 1 |
| [Row 3] EXTIM [EXTIM] | | 11:43 |
| [Row 3] EXCIGRET [EXCIGRET] | | 1 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 3] EXTIMRET [EXTIMRET] | | 11:53 |
| [Row 4] EXPRDT [EXPRDT] | | Combustible Cigarette |
| [Row 4] EXDSPD [EXDSPD] | | 1 |
| [Row 4] EXTIM [EXTIM] | | 12:41 |
| [Row 4] EXCIGRET [EXCIGRET] | | 1 |
| [Row 4] EXTIMRET [EXTIMRET] | | 12:49 |
| [Row 5] EXPRDT [EXPRDT] | | Combustible Cigarette |
| [Row 5] EXDSPD [EXDSPD] | | 1 |
| [Row 5] EXTIM [EXTIM] | | 13:40 |
| [Row 5] EXCIGRET [EXCIGRET] | | 1 |
| [Row 5] EXTIMRET [EXTIMRET] | | 13:49 |

**FORM STATUS CHANGE LOG**

VISIT: Day 3
FORM: Part A - Usual Brand Dose Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 26-Jun-2018 09:27 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:48 AM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 3
FORM: Part A - Usual Brand Dose Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 02-Aug-2018 09:11 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 3
FORM: Part A - Usual Brand Dose Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 3
FORM: Part A - VLN Dosing Log

| | |
|---|---|
| AD LIB VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG | |
| Date of Visit: [EXDAT] | |
| Row 1 | |
| Product Used: [EXPRDT] | |
| Number Dispensed: [EXDSPD] | |

| | |
|---|---|
| Time Dispensed:<br>[EXTIM] | |
| Number of Butts Returned:<br>[EXCIGRET] | |
| Time Returned:<br>[EXTIMRET] | |

**FORM STATUS CHANGE LOG**

VISIT: Day 3
FORM: Part A - VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Day 3
FORM: Part A - VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 3
FORM: Part A - Nicorette Dosing Log

| | |
|---|---|
| AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG | |
| Date of Visit:<br>[EXDAT] | |
| Row 1 | |
| Product Used:<br>[EXPRDT] | |

| | |
|---|---|
| Number Dispensed:<br>[EXDSPD] | |
| Time Dispensed:<br>[EXTIM] | |
| Number of Pieces Returned:<br>[EXNICRET] | |
| Time Returned/Discarded:<br>[EXTIMRET] | |

## FORM STATUS CHANGE LOG

VISIT: Day 3
FORM: Part A - Nicorette Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 3
FORM: Part A - Nicorette Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 3
FORM: Use Product Again - VAS

| | |
|---|---|
| Was Questionnaire performed?<br>[QSPERF] | Yes |
| Use:<br>[QSUSE] | 1st Use |

## AUDIT TRAIL

VISIT: Day 3
FORM: Use Product Again - VAS

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 26-Jun-2018 08:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF [QSPERF] | | Yes |
| QS5USE [QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 3
FORM: Use Product Again - VAS

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 26-Jun-2018 08:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 3
FORM: Use Product Again - VAS

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 3
FORM: Use Product Again - VAS

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Visit Date

| | |
|---|---|
| Visit Done? [SVYN] | Yes |
| Date of Visit: [SVSTDAT] | 26-Jun-2018 |

## AUDIT TRAIL

VISIT: Day 4
FORM: Visit Date

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 27-Jun-2018 12:36 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN [SVYN] | | Yes |
| SVSTDAT [SVSTDAT] | | 26-Jun-2018 |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Visit Date

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 27-Jun-2018 12:36 PM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: Visit Date

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Randomization

| | |
|---|---|
| Date of Randomization: [DSRDAT] | 26-Jun-2018 |
| Randomization Number: [DSNUM] | 2040 |
| Sequence Group [DSRNGRP] | BCA |

## AUDIT TRAIL

VISIT: Day 4
FORM: Randomization

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
| **Date/Time** | 27-Jun-2018 12:34 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| DSRNDAT [DSRDAT] | | 26-Jun-2018 |
| DSRNUM [DSNUM] | | 2040 |
| DSRNGRP [DSRNGRP] | | BCA |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Randomization

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 27-Jun-2018 12:34 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: Randomization

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: Randomization

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-1

| | |
|---|---|
| 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: [EXNICDAT] | |
| Row 1 | |
| Product: [EXPRDB] | |
| Session Start Time: [EXSRTTIMB] | |
| Session End Time: [EXENTMB] | |
| | |
| Did the subject consume any beverages during controlled product use?: [EXBEV] | |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-1

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-1

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Part B - Uncontrolled Nicorette Dosing Log

| | |
|---|---|
| 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: [EXNICDAT] | |
| Row 1 | |
| Product: [EXPRDB] | |
| Session Start Time: [EXSRTTIMB] | |
| Session End Time: [EXENTMB] | |
| | |
| Did the subject consume any beverages during controlled product use?: [EXBEV] | |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Part B - Uncontrolled Nicorette Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 4
FORM: Part B - Uncontrolled Nicorette Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| | |
|---|---|
| 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: [EXDATB] | 26-Jun-2018 |
| Session Start Time: [EXSRTTIM] | 16:00 |
| Session End Time: [EXENDTIM] | 16:06 |
| Row 1 | |
| Inhalation Begin: [EXINHBG] | 16:00:00 |
| Time Unknown: [EXTIMUNK] | |

| | |
|---|---|
| Inhalation End: [EXINEN] | 16:00:05 |
| Time Unknown: [EXTIMUNK] | |
| Row 2 | |
| Inhalation Begin: [EXINHBG] | 16:00:16 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:00:20 |
| Time Unknown: [EXTIMUNK] | |
| Row 3 | |
| Inhalation Begin: [EXINHBG] | 16:00:36 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:00:38 |
| Time Unknown: [EXTIMUNK] | |
| Row 4 | |
| Inhalation Begin: [EXINHBG] | 16:01:08 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:01:11 |
| Time Unknown: [EXTIMUNK] | |
| Row 5 | |
| Inhalation Begin: [EXINHBG] | 16:01:21 |

| | |
|---|---|
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:01:24 |
| Time Unknown: [EXTIMUNK] | |
| Row 6 | |
| Inhalation Begin: [EXINHBG] | 16:01:42 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:01:46 |
| Time Unknown: [EXTIMUNK] | |
| Row 7 | |
| Inhalation Begin: [EXINHBG] | 16:02:04 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:02:07 |
| Time Unknown: [EXTIMUNK] | |
| Row 8 | |
| Inhalation Begin: [EXINHBG] | 16:02:25 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:02:30 |
| Time Unknown: [EXTIMUNK] | |

| | |
|---|---|
| Row 9 | |
| Inhalation Begin: [EXINHBG] | 16:02:47 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:02:50 |
| Time Unknown: [EXTIMUNK] | |
| Row 10 | |
| Inhalation Begin: [EXINHBG] | 16:03:19 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:03:23 |
| Time Unknown: [EXTIMUNK] | |
| Row 11 | |
| Inhalation Begin: [EXINHBG] | 16:03:36 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:03:39 |
| Time Unknown: [EXTIMUNK] | |
| Row 12 | |
| Inhalation Begin: [EXINHBG] | 16:04:12 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:04:14 |

| | |
|---|---|
| Time Unknown: [EXTIMUNK] | |
| Row 13 | |
| Inhalation Begin: [EXINHBG] | 16:04:47 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:04:49 |
| Time Unknown: [EXTIMUNK] | |
| Row 14 | |
| Inhalation Begin: [EXINHBG] | 16:05:18 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:05:20 |
| Time Unknown: [EXTIMUNK] | |
| Row 15 | |
| Inhalation Begin: [EXINHBG] | 16:05:28 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:05:31 |
| Time Unknown: [EXTIMUNK] | |
| Row 16 | |
| Inhalation Begin: [EXINHBG] | 16:05:42 |
| Time Unknown: [EXTIMUNK] | |

| | |
|---|---|
| Inhalation End:<br>[EXINEN] | 16:05:44 |
| Time Unknown:<br>[EXTIMUNK] | |
| Row 17 | |
| Inhalation Begin:<br>[EXINHBG] | 16:06:01 |
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | 16:06:04 |
| Time Unknown:<br>[EXTIMUNK] | |
| Row 18 | |
| Inhalation Begin:<br>[EXINHBG] | 16:06:19 |
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | 16:06:22 |
| Time Unknown:<br>[EXTIMUNK] | |
| Row 19 | |
| Inhalation Begin:<br>[EXINHBG] | 16:06:41 |
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | 16:06:44 |
| Time Unknown:<br>[EXTIMUNK] | |
| Row 20 | |
| Inhalation Begin:<br>[EXINHBG] | 16:06:52 |

| | |
|---|---|
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | 16:06:53 |
| Time Unknown:<br>[EXTIMUNK] | |

| | |
|---|---|
| Did the subject consume any beverages during uncontrolled product use?<br>[EXBEVB] | No |
| Session Total Inhalations:<br>[EXINTOT] | 20 |

**AUDIT TRAIL**

VISIT: Day 4
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 27-Jun-2018 12:46 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EXDATB<br>[EXDATB] | | 26-Jun-2018 |
| EXSRTTIM<br>[EXSRTTIM] | | 16:00 |
| EXENDTIM<br>[EXENDTIM] | | 16:06 |
| [Row 1] EXINHBG<br>[EXINHBG] | | 16:00:00 |
| [Row 1] EXINEN<br>[EXINEN] | | 16:00:05 |
| [Row 2] EXINHBG<br>[EXINHBG] | | 16:00:16 |
| [Row 2] EXINEN<br>[EXINEN] | | 16:00:20 |
| [Row 3] EXINHBG<br>[EXINHBG] | | 16:00:36 |
| [Row 3] EXINEN<br>[EXINEN] | | 16:00:38 |
| [Row 4] EXINHBG | | 16:01:08 |

| Variable | Old Value | New Value |
|---|---|---|
| [EXINHBG] | | |
| [Row 4] EXINEN [EXINEN] | | 16:01:11 |
| [Row 5] EXINHBG [EXINHBG] | | 16:01:21 |
| [Row 5] EXINEN [EXINEN] | | 16:01:24 |
| [Row 6] EXINHBG [EXINHBG] | | 16:01:42 |
| [Row 6] EXINEN [EXINEN] | | 16:01:46 |
| [Row 7] EXINHBG [EXINHBG] | | 16:02:04 |
| [Row 7] EXINEN [EXINEN] | | 16:02:07 |
| [Row 8] EXINHBG [EXINHBG] | | 16:02:25 |
| [Row 8] EXINEN [EXINEN] | | 16:02:30 |
| [Row 9] EXINHBG [EXINHBG] | | 16:02:47 |
| [Row 9] EXINEN [EXINEN] | | 16:02:50 |
| [Row 10] EXINHBG [EXINHBG] | | 16:03:19 |
| [Row 10] EXINEN [EXINEN] | | 16:03:23 |
| [Row 11] EXINHBG [EXINHBG] | | 16:03:36 |
| [Row 11] EXINEN [EXINEN] | | 16:03:39 |
| [Row 12] EXINHBG [EXINHBG] | | 16:04:12 |
| [Row 12] EXINEN [EXINEN] | | 16:04:14 |
| [Row 13] EXINHBG [EXINHBG] | | 16:04:47 |
| [Row 13] EXINEN [EXINEN] | | 16:04:49 |
| [Row 14] EXINHBG [EXINHBG] | | 16:05:18 |
| [Row 14] EXINEN [EXINEN] | | 16:05:20 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 15] EXINHBG [EXINHBG] | | 16:05:28 |
| [Row 15] EXINEN [EXINEN] | | 16:05:31 |
| [Row 16] EXINHBG [EXINHBG] | | 16:05:42 |
| [Row 16] EXINEN [EXINEN] | | 16:05:44 |
| [Row 17] EXINHBG [EXINHBG] | | 16:06:01 |
| [Row 17] EXINEN [EXINEN] | | 16:06:04 |
| [Row 18] EXINHBG [EXINHBG] | | 16:06:19 |
| [Row 18] EXINEN [EXINEN] | | 16:06:22 |
| [Row 19] EXINHBG [EXINHBG] | | 16:06:41 |
| [Row 19] EXINEN [EXINEN] | | 16:06:44 |
| [Row 20] EXINHBG [EXINHBG] | | 16:06:52 |
| [Row 20] EXINEN [EXINEN] | | 16:06:53 |
| EXBEVB [EXBEVB] | | No |
| EXINTOT [EXINTOT] | | 20 |

**FORM STATUS CHANGE LOG**

VISIT: Day 4
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 27-Jun-2018 12:46 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 27-Jun-2018 12:34 PM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 4
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 02-Aug-2018 09:13 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Day 4
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 4
FORM: Part B - Controlled Usual Brand Dosing Log

| | |
|---|---|
| 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: [EXDATVLN] | 26-Jun-2018 |
| Session Start Time: [EXSTTIM] | 10:00 |

| | |
|---|---|
| Row 1 | |
| Puff:<br>[EXPFF] | Puff 1 |
| Puff Begin:<br>[EXPFBG] | 10:00:00 |
| Puff End:<br>[EXPFEN] | 10:00:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 2 | |
| Puff:<br>[EXPFF] | Puff 2 |
| Puff Begin:<br>[EXPFBG] | 10:00:30 |
| Puff End:<br>[EXPFEN] | 10:00:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 3 | |
| Puff:<br>[EXPFF] | Puff 3 |
| Puff Begin:<br>[EXPFBG] | 10:01:00 |
| Puff End:<br>[EXPFEN] | 10:01:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Row 4 | |
| Puff:<br>[EXPFF] | Puff 4 |
| Puff Begin:<br>[EXPFBG] | 10:01:30 |
| Puff End:<br>[EXPFEN] | 10:01:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 5 | |
| Puff:<br>[EXPFF] | Puff 5 |
| Puff Begin:<br>[EXPFBG] | 10:02:00 |
| Puff End:<br>[EXPFEN] | 10:02:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 6 | |
| Puff:<br>[EXPFF] | Puff 6 |
| Puff Begin:<br>[EXPFBG] | 10:02:30 |
| Puff End:<br>[EXPFEN] | 10:02:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Row 7 | |
| Puff:<br>[EXPFF] | Puff 7 |
| Puff Begin:<br>[EXPFBG] | 10:03:00 |
| Puff End:<br>[EXPFEN] | 10:03:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 8 | |
| Puff:<br>[EXPFF] | Puff 8 |
| Puff Begin:<br>[EXPFBG] | 10:03:30 |
| Puff End:<br>[EXPFEN] | 10:03:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 9 | |
| Puff:<br>[EXPFF] | Puff 9 |
| Puff Begin:<br>[EXPFBG] | 10:04:00 |
| Puff End:<br>[EXPFEN] | 10:04:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |

| Row 10 | |
|---|---|
| Puff:<br>[EXPFF] | Puff 10 |
| Puff Begin:<br>[EXPFBG] | 10:04:30 |
| Puff End:<br>[EXPFEN] | 10:04:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use?<br>[EXBEVB] | No |

**AUDIT TRAIL**

VISIT: Day 4
FORM: Part B - Controlled Usual Brand Dosing Log

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 27-Jun-2018 12:43 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EX8DATVLN<br>[EXDATVLN] | | 26-Jun-2018 |
| EX8STTIM<br>[EXSTTIM] | | 10:00 |
| [Row 1] EX8PFF<br>[EXPFF] | | Puff 1 |
| [Row 1] EX8PFBG<br>[EXPFBG] | | 10:00:00 |
| [Row 1] EX8PFEN<br>[EXPFEN] | | 10:00:03 |
| [Row 1] EX8MISPF<br>[EXMISPF] | | No |
| [Row 2] EX8PFF<br>[EXPFF] | | Puff 2 |
| [Row 2] EX8PFBG | | 10:00:30 |

| Variable | Old Value | New Value |
|---|---|---|
| [EXPFBG] | | |
| [Row 2] EX8PFEN [EXPFEN] | | 10:00:33 |
| [Row 2] EX8MISPF [EXMISPF] | | No |
| [Row 3] EX8PFF [EXPFF] | | Puff 3 |
| [Row 3] EX8PFBG [EXPFBG] | | 10:01:00 |
| [Row 3] EX8PFEN [EXPFEN] | | 10:01:03 |
| [Row 3] EX8MISPF [EXMISPF] | | No |
| [Row 4] EX8PFF [EXPFF] | | Puff 4 |
| [Row 4] EX8PFBG [EXPFBG] | | 10:01:30 |
| [Row 4] EX8PFEN [EXPFEN] | | 10:01:33 |
| [Row 4] EX8MISPF [EXMISPF] | | No |
| [Row 5] EX8PFF [EXPFF] | | Puff 5 |
| [Row 5] EX8PFBG [EXPFBG] | | 10:02:00 |
| [Row 5] EX8PFEN [EXPFEN] | | 10:02:03 |
| [Row 5] EX8MISPF [EXMISPF] | | No |
| [Row 6] EX8PFF [EXPFF] | | Puff 6 |
| [Row 6] EX8PFBG [EXPFBG] | | 10:02:30 |
| [Row 6] EX8PFEN [EXPFEN] | | 10:02:33 |
| [Row 6] EX8MISPF [EXMISPF] | | No |
| [Row 7] EX8PFF [EXPFF] | | Puff 7 |
| [Row 7] EX8PFBG [EXPFBG] | | 10:03:00 |
| [Row 7] EX8PFEN [EXPFEN] | | 10:03:03 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 7] EX8MISPF [EXMISPF] | | No |
| [Row 8] EX8PFF [EXPFF] | | Puff 8 |
| [Row 8] EX8PFBG [EXPFBG] | | 10:03:30 |
| [Row 8] EX8PFEN [EXPFEN] | | 10:03:33 |
| [Row 8] EX8MISPF [EXMISPF] | | No |
| [Row 9] EX8PFF [EXPFF] | | Puff 9 |
| [Row 9] EX8PFBG [EXPFBG] | | 10:04:00 |
| [Row 9] EX8PFEN [EXPFEN] | | 10:04:03 |
| [Row 9] EX8MISPF [EXMISPF] | | No |
| [Row 10] EX8PFF [EXPFF] | | Puff 10 |
| [Row 10] EX8PFBG [EXPFBG] | | 10:04:30 |
| [Row 10] EX8PFEN [EXPFEN] | | 10:04:33 |
| [Row 10] EX8MISPF [EXMISPF] | | No |
| EX8BEVB [EXBEVB] | | No |

**FORM STATUS CHANGE LOG**

VISIT: Day 4
FORM: Part B - Controlled Usual Brand Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 27-Jun-2018 12:43 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 27-Jun-2018 12:34 PM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: Part B - Controlled Usual Brand Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 02-Aug-2018 09:12 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: Part B - Controlled Usual Brand Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Part B - Controlled VLN Dosing Log

| | |
|---|---|
| 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: [EXDATVLN] | |
| Session Start Time: [EXSTTIM] | |

| Row 1 | |
|---|---|
| Puff:<br>[EXPFF] | |
| Puff Begin:<br>[EXPFBG] | |
| Puff End:<br>[EXPFEN] | |
| Missed Puff:<br>[EXMISPF] | |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use?<br>[EXBEVB2] | |

**FORM STATUS CHANGE LOG**

VISIT: Day 4
FORM: Part B - Controlled VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Day 4
FORM: Part B - Controlled VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Part B - Uncontrolled VLN Dosing Log

| | |
|---|---|
| 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) | |
| Date of Visit:<br>[EXDATB] | |
| Session Start Time:<br>[EXSRTTIM] | |
| Session End Time:<br>[EXENDTIM] | |

| Row 1 | |
|---|---|
| Inhalation Begin:<br>[EXINHBG] | |
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | |
| Time Unknown:<br>[EXTIMUNK] | |

| | |
|---|---|
| Did the subject consume any beverages during uncontrolled product use?<br>[EXBEVB] | |
| Session Total Inhalations:<br>[EXINTOT] | |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Part B - Uncontrolled VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 4
FORM: Part B - Uncontrolled VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 1st Use |
| Row 1 | |
| Time point: [QSTMPT] | |
| Completed: [QSYN] | |

## AUDIT TRAIL

VISIT: Day 4
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF [QSPERF] | | Yes |

| Variable | Old Value | New Value |
|---|---|---|
| QSUSE<br>[QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points:<br>[QSPERF] | Yes |
| Use:<br>[QSUSE] | 2nd Use |

| Row 1 | |
|---|---|
| Time point:<br>[QSTMPT] | |
| Completed:<br>[QSYN] | |

## AUDIT TRAIL

VISIT: Day 4
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF1<br>[QSPERF] | | Yes |
| QSUSE_1<br>[QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: 1st Use - Direct Effects of Product Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 1st Use |
| Row 1 | |
| Time point: [QSTMPT] | |
| Completed: [QSYN] | |

## AUDIT TRAIL

VISIT: Day 4
FORM: 1st Use - Direct Effects of Product Questionnaire

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF_1 [QSPERF] | | Yes |
| QSUSE_2 [QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: 1st Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: 1st Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: 1st Use - Direct Effects of Product Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: 2nd Use - Direct Effects of Product Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 2nd Use |
| Row 1 | |
| Time point: [QSTMPT] | |
| Completed: [QSYN] | |

## AUDIT TRAIL

VISIT: Day 4
FORM: 2nd Use - Direct Effects of Product Questionnaire

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF2 [QSPERF] | | Yes |
| QSUSE2 [QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: 2nd Use - Direct Effects of Product Questionnaire

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: 2nd Use - Direct Effects of Product Questionnaire

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: 2nd Use - Direct Effects of Product Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: 1st Use - PK Blood Sampling

| | |
|---|---|
| Use: [PKUSE] | 1st Use (Morning Draw) |

| | |
|---|---|
| Row 1 | |
| Timepoint:<br>[PKTPT] | Predose |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 09:55 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 2 | |
| Timepoint:<br>[PKTPT] | 2 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:02 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 3 | |
| Timepoint:<br>[PKTPT] | 5 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:06 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 4 | |
| Timepoint:<br>[PKTPT] | 7 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:07 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 5 | |
| Timepoint:<br>[PKTPT] | 10 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:10 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 6 | |
| Timepoint:<br>[PKTPT] | 12 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:12 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 7 | |
| Timepoint:<br>[PKTPT] | 15 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:16 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 8 | |
| Timepoint:<br>[PKTPT] | 20 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:20 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |
| Row 9 | |
| Timepoint:<br>[PKTPT] | 30 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 10 | |
| Timepoint:<br>[PKTPT] | 45 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 10:45 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 11 | |
| Timepoint:<br>[PKTPT] | 60 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 11:01 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 12 | |
| Timepoint:<br>[PKTPT] | 90 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 11:32 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 13 | |
| Timepoint:<br>[PKTPT] | 120 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 12:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 14 | |
| Timepoint:<br>[PKTPT] | 150 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 12:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 15 | |
| Timepoint:<br>[PKTPT] | 180 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 13:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |

**AUDIT TRAIL**

VISIT: Day 4
FORM: 1st Use - PK Blood Sampling

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 28-Jun-2018 09:17 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PKUSE1<br>[PKUSE] | | 1st Use (Morning Draw) |
| [Row 1] PKTPT<br>[PKTPT] | | Predose |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 1] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 1] PKTIM [PKTIM] | | 09:55 |
| [Row 2] PKTPT [PKTPT] | | 2 minute |
| [Row 2] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 2] PKTIM [PKTIM] | | 10:02 |
| [Row 3] PKTPT [PKTPT] | | 5 minute |
| [Row 3] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 3] PKTIM [PKTIM] | | 10:06 |
| [Row 3] PKCODE [PKCODE] | | B - Late due to previous procedure |
| [Row 4] PKTPT [PKTPT] | | 7 minute |
| [Row 4] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 4] PKTIM [PKTIM] | | 10:07 |
| [Row 5] PKTPT [PKTPT] | | 10 minute |
| [Row 5] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 5] PKTIM [PKTIM] | | 10:10 |
| [Row 6] PKTPT [PKTPT] | | 12 minute |
| [Row 6] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 6] PKTIM [PKTIM] | | 10:12 |
| [Row 7] PKTPT [PKTPT] | | 15 minute |
| [Row 7] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 7] PKTIM [PKTIM] | | 10:16 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 7] PKCODE [PKCODE] | | B - Late due to previous procedure |
| [Row 8] PKTPT [PKTPT] | | 20 minute |
| [Row 8] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 8] PKTIM [PKTIM] | | 10:20 |
| [Row 9] PKTPT [PKTPT] | | 30 minute |
| [Row 9] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 9] PKTIM [PKTIM] | | 10:30 |
| [Row 10] PKTPT [PKTPT] | | 45 minute |
| [Row 10] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 10] PKTIM [PKTIM] | | 10:45 |
| [Row 11] PKTPT [PKTPT] | | 60 minute |
| [Row 11] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 11] PKTIM [PKTIM] | | 11:01 |
| [Row 11] PKCODE [PKCODE] | | B - Late due to previous procedure |
| [Row 12] PKTPT [PKTPT] | | 90 minute |
| [Row 12] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 12] PKTIM [PKTIM] | | 11:32 |
| [Row 12] PKCODE [PKCODE] | | B - Late due to previous procedure |
| [Row 13] PKTPT [PKTPT] | | 120 minute |
| [Row 13] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 13] PKTIM [PKTIM] | | 12:00 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 14] PKTPT [PKTPT] | | 150 minute |
| [Row 14] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 14] PKTIM [PKTIM] | | 12:30 |
| [Row 15] PKTPT [PKTPT] | | 180 minute |
| [Row 15] PKDAT [PKDAT] | | 26-Jun-2018 |
| [Row 15] PKTIM [PKTIM] | | 13:00 |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: 1st Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:17 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: 1st Use - PK Blood Sampling

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: 1st Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: 2nd Use - PK Blood Sampling

| | |
|---|---|
| Use:<br>[PKUSE] | 2nd Use (Afternoon Draw) |
| Row 1 | |
| Timepoint:<br>[PKTPT] | Predose |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 15:55 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 2 | |
| Timepoint:<br>[PKTPT] | 2 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:02 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 3 | |
| Timepoint:<br>[PKTPT] | 5 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:06 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 4 | |
| Timepoint:<br>[PKTPT] | 7 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:07 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 5 | |
| Timepoint:<br>[PKTPT] | 10 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:10 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 6 | |
| Timepoint:<br>[PKTPT] | 12 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:12 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 7 | |
| Timepoint:<br>[PKTPT] | 15 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:15 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |
| Row 8 | |
| Timepoint:<br>[PKTPT] | 20 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:20 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 9 | |
| Timepoint:<br>[PKTPT] | 30 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:31 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 10 | |
| Timepoint:<br>[PKTPT] | 45 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 16:45 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 11 | |
| Timepoint:<br>[PKTPT] | 60 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 17:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 12 | |
| Timepoint:<br>[PKTPT] | 90 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 17:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 13 | |
| Timepoint:<br>[PKTPT] | 120 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 18:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 14 | |
| Timepoint:<br>[PKTPT] | 150 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 18:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 15 | |
| Timepoint:<br>[PKTPT] | 180 minute |
| Date:<br>[PKDAT] | 26-Jun-2018 |
| Time:<br>[PKTIM] | 19:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |

**AUDIT TRAIL**

VISIT: Day 4
FORM: 2nd Use - PK Blood Sampling

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PKUSE<br>[PKUSE] | | 2nd Use (Afternoon Draw) |
| [Row 1] PKTPT1<br>[PKTPT] | | Predose |
| [Row 1] PKDAT1<br>[PKDAT] | | 26-Jun-2018 |
| [Row 1] PKTIM1<br>[PKTIM] | | 15:55 |
| [Row 2] PKTPT1<br>[PKTPT] | | 2 minute |
| [Row 2] PKDAT1<br>[PKDAT] | | 26-Jun-2018 |
| [Row 2] PKTIM1<br>[PKTIM] | | 16:02 |
| [Row 3] PKTPT1<br>[PKTPT] | | 5 minute |
| [Row 3] PKDAT1<br>[PKDAT] | | 26-Jun-2018 |
| [Row 3] PKTIM1<br>[PKTIM] | | 16:06 |
| [Row 3] PKCODE1<br>[PKCODE] | | B - Late due to previous procedure |
| [Row 4] PKTPT1<br>[PKTPT] | | 7 minute |
| [Row 4] PKDAT1<br>[PKDAT] | | 26-Jun-2018 |
| [Row 4] PKTIM1<br>[PKTIM] | | 16:07 |
| [Row 5] PKTPT1<br>[PKTPT] | | 10 minute |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 5] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 5] PKTIM1 [PKTIM] | | 16:10 |
| [Row 6] PKTPT1 [PKTPT] | | 12 minute |
| [Row 6] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 6] PKTIM1 [PKTIM] | | 16:12 |
| [Row 7] PKTPT1 [PKTPT] | | 15 minute |
| [Row 7] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 7] PKTIM1 [PKTIM] | | 16:15 |
| [Row 8] PKTPT1 [PKTPT] | | 20 minute |
| [Row 8] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 8] PKTIM1 [PKTIM] | | 16:20 |
| [Row 9] PKTPT1 [PKTPT] | | 30 minute |
| [Row 9] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 9] PKTIM1 [PKTIM] | | 16:31 |
| [Row 9] PKCODE1 [PKCODE] | | B - Late due to previous procedure |
| [Row 10] PKTPT1 [PKTPT] | | 45 minute |
| [Row 10] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 10] PKTIM1 [PKTIM] | | 16:45 |
| [Row 11] PKTPT1 [PKTPT] | | 60 minute |
| [Row 11] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 11] PKTIM1 [PKTIM] | | 17:00 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 12] PKTPT1 [PKTPT] | | 90 minute |
| [Row 12] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 12] PKTIM1 [PKTIM] | | 17:30 |
| [Row 13] PKTPT1 [PKTPT] | | 120 minute |
| [Row 13] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 13] PKTIM1 [PKTIM] | | 18:00 |
| [Row 14] PKTPT1 [PKTPT] | | 150 minute |
| [Row 14] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 14] PKTIM1 [PKTIM] | | 18:30 |
| [Row 15] PKTPT1 [PKTPT] | | 180 minute |
| [Row 15] PKDAT1 [PKDAT] | | 26-Jun-2018 |
| [Row 15] PKTIM1 [PKTIM] | | 19:00 |

**FORM STATUS CHANGE LOG**

VISIT: Day 4
FORM: 2nd Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: 2nd Use - PK Blood Sampling

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: 2nd Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Use Product Again - VAS 1st use

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |
| Use: [QSUSE] | 1st Use |

## AUDIT TRAIL

VISIT: Day 4
FORM: Use Product Again - VAS 1st use

| Logged in User | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| Date/Time | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | |
| Application Used | Web Browser (EDC) | |
| Subject Entry | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF [QSPERF] | | Yes |
| QS5USE [QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Use Product Again - VAS 1st use

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:20 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 4
FORM: Use Product Again - VAS 1st use

| User | Date/Time | Status |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 4
FORM: Use Product Again - VAS 1st use

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 4
FORM: Use Product Again - VAS 2nd use

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |
| Use: [QSUSE] | 2nd Use |

## AUDIT TRAIL

VISIT: Day 4
FORM: Use Product Again - VAS 2nd use

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:21 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF [QSPERF] | | Yes |
| QS5USE [QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Use Product Again - VAS 2nd use

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:21 AM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 4
FORM: Use Product Again - VAS 2nd use

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:30 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Day 4
FORM: Use Product Again - VAS 2nd use

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 5
FORM: Visit Date

| | |
|---|---|
| Visit Done? [SVYN] | Yes |
| Date of Visit: [SVSTDAT] | 27-Jun-2018 |

## AUDIT TRAIL

VISIT: Day 5
FORM: Visit Date

| Logged in User | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| Date/Time | 28-Jun-2018 09:21 AM PDT (UTC-07:00) | |
| Application Used | Web Browser (EDC) | |
| Subject Entry | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN [SVYN] | | Yes |
| SVSTDAT [SVSTDAT] | | 27-Jun-2018 |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: Visit Date

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:21 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: Visit Date

| User | Date/Time | Status |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: Part B - Controlled Nicorette Dosing Log

| | |
|---|---|
| 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: [EXNICDAT] | 27-Jun-2018 |
| Row 1 | |
| Product: [EXPRDB] | Nicorette Original Flavor Gum (4 mg) |
| Session Start Time: [EXSRTTIMB] | 10:00 |
| Session End Time: [EXENTMB] | 10:10 |
| | |
| Did the subject consume any beverages during controlled product use?: [EXBEV] | No |

## AUDIT TRAIL

VISIT: Day 5
FORM: Part B - Controlled Nicorette Dosing Log

| | |
|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) |
| **Date/Time** | 28-Jun-2018 02:04 PM PDT (UTC-07:00) |

| Application Used | Web Browser (EDC) | |
|---|---|---|
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EXNICDAT [EXNICDAT] | | 27-Jun-2018 |
| [Row 1] EXPRDB [EXPRDB] | | Nicorette Original Flavor Gum (4 mg) |
| [Row 1] EXSRTTIMB [EXSRTTIMB] | | 10:00 |
| [Row 1] EXENTMB [EXENTMB] | | 10:10 |
| EXBEV [EXBEV] | | No |

**FORM STATUS CHANGE LOG**

VISIT: Day 5
FORM: Part B - Controlled Nicorette Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 02:04 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 5
FORM: Part B - Controlled Nicorette Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 02-Aug-2018 09:14 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: Part B - Controlled Nicorette Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: Part B - Uncontrolled Nicorette Dosing Log

| | |
|---|---|
| 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: [EXNICDAT] | 27-Jun-2018 |
| Row 1 | |
| Product: [EXPRDB] | Nicorette Original Flavor Gum (4 mg) |
| Session Start Time: [EXSRTTIMB] | 16:00 |
| Session End Time: [EXENTMB] | 16:06 |
| | |
| Did the subject consume any beverages during controlled product use?: [EXBEV] | No |

## AUDIT TRAIL

VISIT: Day 5
FORM: Part B - Uncontrolled Nicorette Dosing Log

| | |
|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) |
| **Date/Time** | 28-Jun-2018 02:05 PM PDT (UTC-07:00) |

| Application Used | Web Browser (EDC) | |
|---|---|---|
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EXNICDAT2 [EXNICDAT] | | 27-Jun-2018 |
| [Row 1] EXPRDB2 [EXPRDB] | | Nicorette Original Flavor Gum (4 mg) |
| [Row 1] EXSRTTIMB2 [EXSRTTIMB] | | 16:00 |
| [Row 1] EXENTMB2 [EXENTMB] | | 16:06 |
| EXBEV2 [EXBEV] | | No |

**FORM STATUS CHANGE LOG**

VISIT: Day 5
FORM: Part B - Uncontrolled Nicorette Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 02:05 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 27-Jun-2018 12:34 PM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 5
FORM: Part B - Uncontrolled Nicorette Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com ((b) (6) (b) (6) | 02-Aug-2018 09:14 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: Part B - Uncontrolled Nicorette Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| | |
|---|---|
| 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: [EXDATB] | |
| Session Start Time: [EXSRTTIM] | |
| Session End Time: [EXENDTIM] | |
| Row 1 | |
| Inhalation Begin: [EXINHBG] | |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | |
| Time Unknown: [EXTIMUNK] | |

| | |
|---|---|
| Did the subject consume any beverages during uncontrolled product use? [EXBEVB] | |
| Session Total Inhalations: [EXINTOT] | |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 5
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: Part B - Controlled Usual Brand Dosing Log

| | |
|---|---|
| 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: [EXDATVLN] | |
| Session Start Time: [EXSTTIM] | |

| Row 1 | |
|---|---|
| Puff:<br>[EXPFF] | |
| Puff Begin:<br>[EXPFBG] | |
| Puff End:<br>[EXPFEN] | |
| Missed Puff:<br>[EXMISPF] | |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use?<br>[EXBEVB] | |

**FORM STATUS CHANGE LOG**

VISIT: Day 5
FORM: Part B - Controlled Usual Brand Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Day 5
FORM: Part B - Controlled Usual Brand Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 5
FORM: Part B - Controlled VLN Dosing Log

| | |
|---|---|
| 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:<br>[EXDATVLN] | |
| Session Start Time:<br>[EXSTTIM] | |

| Row 1 | |
|---|---|
| Puff:<br>[EXPFF] | |
| Puff Begin:<br>[EXPFBG] | |
| Puff End:<br>[EXPFEN] | |
| Missed Puff:<br>[EXMISPF] | |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use?<br>[EXBEVB2] | |

**FORM STATUS CHANGE LOG**

VISIT: Day 5
FORM: Part B - Controlled VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 5
FORM: Part B - Controlled VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: Part B - Uncontrolled VLN Dosing Log

| | |
|---|---|
| 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) | |
| Date of Visit: [EXDATB] | |
| Session Start Time: [EXSRTTIM] | |
| Session End Time: [EXENDTIM] | |
| Row 1 | |
| Inhalation Begin: [EXINHBG] | |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | |
| Time Unknown: [EXTIMUNK] | |
| | |
| Did the subject consume any beverages during uncontrolled product use? [EXBEVB] | |

| | |
|---|---|
| Session Total Inhalations:<br>[EXINTOT] | |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: Part B - Uncontrolled VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 5
FORM: Part B - Uncontrolled VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points:<br>[QSPERF] | Yes |
| Use:<br>[QSUSE] | 1st Use |
| Row 1 | |
| Time point:<br>[QSTMPT] | |
| Completed:<br>[QSYN] | |

## AUDIT TRAIL

VISIT: Day 5
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF [QSPERF] | | Yes |
| QSUSE [QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 2nd Use |
| Row 1 | |
| Time point: [QSTMPT] | |
| Completed: [QSYN] | |

## AUDIT TRAIL

VISIT: Day 5
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF1 [QSPERF] | | Yes |
| QSUSE_1 [QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: 1st Use - Direct Effects of Product Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |

| | |
|---|---|
| Use:<br>[QSUSE] | 1st Use |

| Row 1 | |
|---|---|
| Time point:<br>[QSTMPT] | |
| Completed:<br>[QSYN] | |

**AUDIT TRAIL**

VISIT: Day 5
FORM: 1st Use - Direct Effects of Product Questionnaire

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF_1<br>[QSPERF] | | Yes |
| QSUSE_2<br>[QSUSE] | | 1st Use |

**FORM STATUS CHANGE LOG**

VISIT: Day 5
FORM: 1st Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: 1st Use - Direct Effects of Product Questionnaire

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: 1st Use - Direct Effects of Product Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: 2nd Use - Direct Effects of Product Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 2nd Use |

| Row 1 | |
|---|---|
| Time point: [QSTMPT] | |
| Completed: [QSYN] | |

## AUDIT TRAIL

VISIT: Day 5
FORM: 2nd Use - Direct Effects of Product Questionnaire

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF2 [QSPERF] | | Yes |
| QSUSE2 [QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: 2nd Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: 2nd Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: 2nd Use - Direct Effects of Product Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: 1st Use - PK Blood Sampling

| | |
|---|---|
| Use:<br>[PKUSE] | 1st Use (Morning Draw) |
| Row 1 | |
| Timepoint:<br>[PKTPT] | Predose |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 09:55 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 2 | |
| Timepoint:<br>[PKTPT] | 2 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:02 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 3 | |
| Timepoint:<br>[PKTPT] | 5 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:05 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 4 | |
| Timepoint:<br>[PKTPT] | 7 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:07 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 5 | |
| Timepoint:<br>[PKTPT] | 10 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:10 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 6 | |
| Timepoint:<br>[PKTPT] | 12 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:12 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 7 | |
| Timepoint:<br>[PKTPT] | 15 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:16 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 8 | |
| Timepoint:<br>[PKTPT] | 20 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:20 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 9 | |
| Timepoint:<br>[PKTPT] | 30 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 10 | |
| Timepoint:<br>[PKTPT] | 45 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 10:45 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 11 | |
| Timepoint:<br>[PKTPT] | 60 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 11:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 12 | |
| Timepoint:<br>[PKTPT] | 90 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 11:31 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 13 | |
| Timepoint:<br>[PKTPT] | 120 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 12:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 14 | |
| Timepoint:<br>[PKTPT] | 150 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 12:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 15 | |
| Timepoint:<br>[PKTPT] | 180 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 13:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |

**AUDIT TRAIL**

VISIT: Day 5
FORM: 1st Use - PK Blood Sampling

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:23 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PKUSE1<br>[PKUSE] | | 1st Use (Morning Draw) |
| [Row 1] PKTPT<br>[PKTPT] | | Predose |
| [Row 1] PKDAT<br>[PKDAT] | | 27-Jun-2018 |
| [Row 1] PKTIM<br>[PKTIM] | | 09:55 |
| [Row 2] PKTPT<br>[PKTPT] | | 2 minute |
| [Row 2] PKDAT<br>[PKDAT] | | 27-Jun-2018 |
| [Row 2] PKTIM<br>[PKTIM] | | 10:02 |
| [Row 3] PKTPT<br>[PKTPT] | | 5 minute |
| [Row 3] PKDAT<br>[PKDAT] | | 27-Jun-2018 |
| [Row 3] PKTIM<br>[PKTIM] | | 10:05 |
| [Row 4] PKTPT<br>[PKTPT] | | 7 minute |
| [Row 4] PKDAT<br>[PKDAT] | | 27-Jun-2018 |
| [Row 4] PKTIM<br>[PKTIM] | | 10:07 |
| [Row 5] PKTPT<br>[PKTPT] | | 10 minute |
| [Row 5] PKDAT<br>[PKDAT] | | 27-Jun-2018 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 5] PKTIM [PKTIM] | | 10:10 |
| [Row 6] PKTPT [PKTPT] | | 12 minute |
| [Row 6] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 6] PKTIM [PKTIM] | | 10:12 |
| [Row 7] PKTPT [PKTPT] | | 15 minute |
| [Row 7] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 7] PKTIM [PKTIM] | | 10:16 |
| [Row 7] PKCODE [PKCODE] | | B - Late due to previous procedure |
| [Row 8] PKTPT [PKTPT] | | 20 minute |
| [Row 8] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 8] PKTIM [PKTIM] | | 10:20 |
| [Row 9] PKTPT [PKTPT] | | 30 minute |
| [Row 9] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 9] PKTIM [PKTIM] | | 10:30 |
| [Row 10] PKTPT [PKTPT] | | 45 minute |
| [Row 10] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 10] PKTIM [PKTIM] | | 10:45 |
| [Row 11] PKTPT [PKTPT] | | 60 minute |
| [Row 11] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 11] PKTIM [PKTIM] | | 11:00 |
| [Row 12] PKTPT [PKTPT] | | 90 minute |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 12] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 12] PKTIM [PKTIM] | | 11:31 |
| [Row 12] PKCODE [PKCODE] | | B - Late due to previous procedure |
| [Row 13] PKTPT [PKTPT] | | 120 minute |
| [Row 13] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 13] PKTIM [PKTIM] | | 12:00 |
| [Row 14] PKTPT [PKTPT] | | 150 minute |
| [Row 14] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 14] PKTIM [PKTIM] | | 12:30 |
| [Row 15] PKTPT [PKTPT] | | 180 minute |
| [Row 15] PKDAT [PKDAT] | | 27-Jun-2018 |
| [Row 15] PKTIM [PKTIM] | | 13:00 |

**FORM STATUS CHANGE LOG**

VISIT: Day 5
FORM: 1st Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:23 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: 1st Use - PK Blood Sampling

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: 1st Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: 2nd Use - PK Blood Sampling

| | |
|---|---|
| Use: [PKUSE] | 2nd Use (Afternoon Draw) |

| Row 1 | |
|---|---|
| Timepoint: [PKTPT] | Predose |
| Date: [PKDAT] | 27-Jun-2018 |
| Time: [PKTIM] | 15:55 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 2 | |
| Timepoint:<br>[PKTPT] | 2 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:02 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 3 | |
| Timepoint:<br>[PKTPT] | 5 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:05 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 4 | |
| Timepoint:<br>[PKTPT] | 7 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:07 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 5 | |
| Timepoint:<br>[PKTPT] | 10 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:10 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 6 | |
| Timepoint:<br>[PKTPT] | 12 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:12 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |
| Row 7 | |
| Timepoint:<br>[PKTPT] | 15 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:15 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 8 | |
| Timepoint:<br>[PKTPT] | 20 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:20 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 9 | |
| Timepoint:<br>[PKTPT] | 30 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:30 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 10 | |
| Timepoint:<br>[PKTPT] | 45 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 16:45 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 11 | |
| Timepoint:<br>[PKTPT] | 60 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 17:01 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 12 | |
| Timepoint:<br>[PKTPT] | 90 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 17:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 13 | |
| Timepoint:<br>[PKTPT] | 120 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 18:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 14 | |
| Timepoint:<br>[PKTPT] | 150 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 18:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |
| Row 15 | |
| Timepoint:<br>[PKTPT] | 180 minute |
| Date:<br>[PKDAT] | 27-Jun-2018 |
| Time:<br>[PKTIM] | 19:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |

**AUDIT TRAIL**

VISIT: Day 5
FORM: 2nd Use - PK Blood Sampling

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:25 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PKUSE<br>[PKUSE] | | 2nd Use (Afternoon Draw) |
| [Row 1] PKTPT1<br>[PKTPT] | | Predose |
| [Row 1] PKDAT1<br>[PKDAT] | | 27-Jun-2018 |
| [Row 1] PKTIM1<br>[PKTIM] | | 15:55 |
| [Row 2] PKTPT1<br>[PKTPT] | | 2 minute |
| [Row 2] PKDAT1<br>[PKDAT] | | 27-Jun-2018 |
| [Row 2] PKTIM1 | | 16:02 |

| Variable | Old Value | New Value |
|---|---|---|
| [PKTIM] | | |
| [Row 3] PKTPT1 [PKTPT] | | 5 minute |
| [Row 3] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 3] PKTIM1 [PKTIM] | | 16:05 |
| [Row 4] PKTPT1 [PKTPT] | | 7 minute |
| [Row 4] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 4] PKTIM1 [PKTIM] | | 16:07 |
| [Row 5] PKTPT1 [PKTPT] | | 10 minute |
| [Row 5] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 5] PKTIM1 [PKTIM] | | 16:10 |
| [Row 6] PKTPT1 [PKTPT] | | 12 minute |
| [Row 6] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 6] PKTIM1 [PKTIM] | | 16:12 |
| [Row 7] PKTPT1 [PKTPT] | | 15 minute |
| [Row 7] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 7] PKTIM1 [PKTIM] | | 16:15 |
| [Row 8] PKTPT1 [PKTPT] | | 20 minute |
| [Row 8] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 8] PKTIM1 [PKTIM] | | 16:20 |
| [Row 9] PKTPT1 [PKTPT] | | 30 minute |
| [Row 9] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 9] PKTIM1 [PKTIM] | | 16:30 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 10] PKTPT1 [PKTPT] | | 45 minute |
| [Row 10] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 10] PKTIM1 [PKTIM] | | 16:45 |
| [Row 11] PKTPT1 [PKTPT] | | 60 minute |
| [Row 11] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 11] PKTIM1 [PKTIM] | | 17:01 |
| [Row 11] PKCODE1 [PKCODE] | | B - Late due to previous procedure |
| [Row 12] PKTPT1 [PKTPT] | | 90 minute |
| [Row 12] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 12] PKTIM1 [PKTIM] | | 17:30 |
| [Row 13] PKTPT1 [PKTPT] | | 120 minute |
| [Row 13] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 13] PKTIM1 [PKTIM] | | 18:00 |
| [Row 14] PKTPT1 [PKTPT] | | 150 minute |
| [Row 14] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 14] PKTIM1 [PKTIM] | | 18:30 |
| [Row 15] PKTPT1 [PKTPT] | | 180 minute |
| [Row 15] PKDAT1 [PKDAT] | | 27-Jun-2018 |
| [Row 15] PKTIM1 [PKTIM] | | 19:00 |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: 2nd Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:25 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: 2nd Use - PK Blood Sampling

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: 2nd Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: Use Product Again - VAS 1st use

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |

| | |
|---|---|
| Use:<br>[QSUSE] | 1st Use |

## AUDIT TRAIL

VISIT: Day 5
FORM: Use Product Again - VAS 1st use

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF<br>[QSPERF] | | Yes |
| QS5USE<br>[QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: Use Product Again - VAS 1st use

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: Use Product Again - VAS 1st use

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: Use Product Again - VAS 1st use

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 5
FORM: Use Product Again - VAS 2nd use

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |
| Use: [QSUSE] | 2nd Use |

## AUDIT TRAIL

VISIT: Day 5
FORM: Use Product Again - VAS 2nd use

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF [QSPERF] | | Yes |
| QS5USE [QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: Use Product Again - VAS 2nd use

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:26 AM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 5
FORM: Use Product Again - VAS 2nd use

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 5
FORM: Use Product Again - VAS 2nd use

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Visit Date

| | |
|---|---|
| Visit Done? [SVYN] | Yes |
| Date of Visit: [SVSTDAT] | 28-Jun-2018 |

## AUDIT TRAIL

VISIT: Day 6
FORM: Visit Date

| Logged in User | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| Date/Time | 28-Jun-2018 09:27 AM PDT (UTC-07:00) | |
| Application Used | Web Browser (EDC) | |
| Subject Entry | No | |
| **Variable** | **Old Value** | **New Value** |
| SVYN [SVYN] | | Yes |
| SVSTDAT [SVSTDAT] | | 28-Jun-2018 |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Visit Date

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 28-Jun-2018 09:27 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Visit Date

| User | Date/Time | Status |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Vital Signs

| | |
|---|---|
| Were vital signs measured? [VSPERF] | Yes |
| Repeat vital signs? [VSPERFR] | No |
| Time Seated: [VS1TIMS] | 19:10 |
| Time Seated Unknown: [VSTIMSUN] | |
| Date: [VSDAT] | 28-Jun-2018 |
| Time Taken: [VSTIM] | 19:15 |
| Time Unknown: [VSTMNK] | |
| Row 1 | |
| Assessment: [VSTEST] | Oral Temperature |
| Not done: [VSSTAT] | |
| Result: [VSORRES] | 37.2 |
| Unit: [VSORRESU] | C |

| | |
|---|---|
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 2 | |
| Assessment:<br>[VSTEST] | Systolic Blood Pressure |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 115 |
| Unit:<br>[VSORRESU] | mmHg |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 3 | |
| Assessment:<br>[VSTEST] | Diastolic Blood Pressure |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 80 |
| Unit:<br>[VSORRESU] | mmHg |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |
| Row 4 | |
| Assessment:<br>[VSTEST] | Pulse Rate |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 71 |
| Unit:<br>[VSORRESU] | beats/min |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |

| Row 5 | |
|---|---|
| Assessment:<br>[VSTEST] | Respirations |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | 16 |
| Unit:<br>[VSORRESU] | breaths/min |
| MD Safety Review:<br>[VSCLSIG] | WITHIN NORMAL RANGE |

**AUDIT TRAIL**

VISIT: Day 6
FORM: Vital Signs

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:58 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| VSPERF<br>[VSPERF] | | Yes |
| VSPERFR<br>[VSPERFR] | | No |
| VSTIMS<br>[VS1TIMS] | | 19:10 |
| VS1DAT<br>[VSDAT] | | 28-Jun-2018 |
| VSTIM<br>[VSTIM] | | 19:15 |
| [Row 1] VSTEST<br>[VSTEST] | | Oral Temperature |
| [Row 1] VSORRES<br>[VSORRES] | | 37.2 |
| [Row 1] VSORRESU<br>[VSORRESU] | | C |
| [Row 1] VSCLSIG<br>[VSCLSIG] | | WITHIN NORMAL RANGE |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 2] VSTEST [VSTEST] | | Systolic Blood Pressure |
| [Row 2] VSORRES [VSORRES] | | 115 |
| [Row 2] VSORRESU [VSORRESU] | | mmHg |
| [Row 2] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 3] VSTEST [VSTEST] | | Diastolic Blood Pressure |
| [Row 3] VSORRES [VSORRES] | | 80 |
| [Row 3] VSORRESU [VSORRESU] | | mmHg |
| [Row 3] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 4] VSTEST [VSTEST] | | Pulse Rate |
| [Row 4] VSORRES [VSORRES] | | 71 |
| [Row 4] VSORRESU [VSORRESU] | | beats/min |
| [Row 4] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |
| [Row 5] VSTEST [VSTEST] | | Respirations |
| [Row 5] VSORRES [VSORRES] | | 16 |
| [Row 5] VSORRESU [VSORRESU] | | breaths/min |
| [Row 5] VSCLSIG [VSCLSIG] | | WITHIN NORMAL RANGE |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Vital Signs

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:58 PM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Vital Signs

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: Vital Signs

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 28-Jun-2018 |
| Time of Collection: [LBTIM] | 19:00 |
| Time Unknown: [LBTMNK] | |

| | |
|---|---|
| Are all results within normal limits? [LBNRIND] | No |

| Row 1 | |
|---|---|
| Test Name: [LBTEST] | Alkaline Phosphatase |
| Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG] | NCS |

**AUDIT TRAIL**

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 02-Jul-2018 10:50 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN2 [LBYN] | | Yes |
| LBDAT5 [LBDAT] | | 28-Jun-2018 |
| LBTIM5 [LBTIM] | | 19:00 |
| LBNRIND5 [LBNRIND] | | No |
| [Row 1] LBTEST [LBTEST] | | Alkaline Phosphatase |
| [Row 1] LBCLSIG5 [LBCLSIG] | | NCS |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 02-Jul-2018 10:50 AM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 28-Jun-2018 |
| Time of Collection: [LBTIM] | 19:00 |
| Time Unknown: [LBTMNK] | |

| | |
|---|---|
| Are all results within normal limits? [LBNRIND] | Yes |
| Row 1 | |
| Test Name: [LBTEST] | |
| Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG] | |

**AUDIT TRAIL**

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 02-Jul-2018 10:50 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN6 [LBYN] | | Yes |
| LBDAT6 [LBDAT] | | 28-Jun-2018 |
| LBTIM6 [LBTIM] | | 19:00 |
| LBNRIND6 [LBNRIND] | | Yes |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 02-Jul-2018 10:50 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

| | |
|---|---|
| Was the laboratory evaluation performed? [LBYN] | Yes |
| Date of collection: [LBDAT] | 28-Jun-2018 |
| Time of Collection: [LBTIM] | 07:11 |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | Yes |

| Row 1 | |
|---|---|
| Test Name:<br>[LBTEST] | |
| Clinical Significance as per MD: (Please record an AE for Clinically Significant results)<br>[LBCLSIG] | |

**AUDIT TRAIL**

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 02-Jul-2018 10:51 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| LBYN3<br>[LBYN] | | Yes |
| LBDAT7<br>[LBDAT] | | 28-Jun-2018 |
| LBTIM7<br>[LBTIM] | | 07:11 |
| LBNRIND7<br>[LBNRIND] | | Yes |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 02-Jul-2018 10:51 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Symptom Directed Physical Exam

| | |
|---|---|
| Was physical examination performed? [PEYN] | No |
| Examination Date: [PEDAT] | |
| Completion Time: [PTIM] | |
| ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM | |

| Row 1 | |
|---|---|
| Body System Examined:<br>[PETEST] | |
| Not done:<br>[PESTAT] | |
| Examination Results:<br>[PEORRES] | |
| Abnormal Findings:<br>[PECLSIG] | |
| | |
| If Other, please specify:<br>[PEOTHSP] | |

**AUDIT TRAIL**

VISIT: Day 6
FORM: Symptom Directed Physical Exam

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:58 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PEYN2<br>[PEYN] | | No |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Symptom Directed Physical Exam

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:58 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: Symptom Directed Physical Exam

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Part B - Controlled Nicorette Dosing Log-1

| | |
|---|---|
| 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: [EXNICDAT] | |
| Row 1 | |
| Product: [EXPRDB] | |
| Session Start Time: [EXSRTTIMB] | |

| | |
|---|---|
| Session End Time:<br>[EXENTMB] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use?:<br>[EXBEV] | |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Part B - Controlled Nicorette Dosing Log-1

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 6
FORM: Part B - Controlled Nicorette Dosing Log-1

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Part B - Uncontrolled Nicorette Dosing Log

| | |
|---|---|
| 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:<br>[EXNICDAT] | |
| Row 1 | |
| Product:<br>[EXPRDB] | |

| | |
|---|---|
| Session Start Time:<br>[EXSRTTIMB] | |
| Session End Time:<br>[EXENTMB] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use?:<br>[EXBEV] | |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Part B - Uncontrolled Nicorette Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Day 6
FORM: Part B - Uncontrolled Nicorette Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 6
FORM: Part B - Controlled Usual Brand Dosing Log

| | |
|---|---|
| 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:<br>[EXDATVLN] | |
| Session Start Time:<br>[EXSTTIM] | |

| Row 1 | |
|---|---|
| Puff:<br>[EXPFF] | |
| Puff Begin:<br>[EXPFBG] | |
| Puff End:<br>[EXPFEN] | |
| Missed Puff:<br>[EXMISPF] | |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use?<br>[EXBEVB] | |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Part B - Controlled Usual Brand Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Day 6
FORM: Part B - Controlled Usual Brand Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 6
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| | |
|---|---|
| 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:<br>[EXDATB] | |
| Session Start Time:<br>[EXSRTTIM] | |
| Session End Time:<br>[EXENDTIM] | |

| Row 1 | |
|---|---|
| Inhalation Begin:<br>[EXINHBG] | |
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | |
| Time Unknown:<br>[EXTIMUNK] | |

| | |
|---|---|
| Did the subject consume any beverages during uncontrolled product use?<br>[EXBEVB] | |
| Session Total Inhalations:<br>[EXINTOT] | |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Day 6
FORM: Part B - Uncontrolled Usual Brand Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Part B - Controlled VLN Dosing Log

| | |
|---|---|
| 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: [EXDATVLN] | 28-Jun-2018 |
| Session Start Time: [EXSTTIM] | 10:00 |
| Row 1 | |
| Puff: [EXPFF] | Puff 1 |
| Puff Begin: [EXPFBG] | 10:00:02 |
| Puff End: [EXPFEN] | 10:00:07 |
| Missed Puff: [EXMISPF] | No |
| If yes, provide reason: [EXCOM] | |

| | |
|---|---|
| Row 2 | |
| Puff:<br>[EXPFF] | Puff 2 |
| Puff Begin:<br>[EXPFBG] | 10:00:30 |
| Puff End:<br>[EXPFEN] | 10:00:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 3 | |
| Puff:<br>[EXPFF] | Puff 3 |
| Puff Begin:<br>[EXPFBG] | 10:01:00 |
| Puff End:<br>[EXPFEN] | 10:01:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 4 | |
| Puff:<br>[EXPFF] | Puff 4 |
| Puff Begin:<br>[EXPFBG] | 10:01:30 |
| Puff End:<br>[EXPFEN] | 10:01:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Row 5 | |
| Puff:<br>[EXPFF] | Puff 5 |
| Puff Begin:<br>[EXPFBG] | 10:02:00 |
| Puff End:<br>[EXPFEN] | 10:02:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 6 | |
| Puff:<br>[EXPFF] | Puff 6 |
| Puff Begin:<br>[EXPFBG] | 10:02:30 |
| Puff End:<br>[EXPFEN] | 10:02:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 7 | |
| Puff:<br>[EXPFF] | Puff 7 |
| Puff Begin:<br>[EXPFBG] | 10:03:01 |
| Puff End:<br>[EXPFEN] | 10:03:04 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Row 8 | |
| Puff:<br>[EXPFF] | Puff 8 |
| Puff Begin:<br>[EXPFBG] | 10:03:30 |
| Puff End:<br>[EXPFEN] | 10:03:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 9 | |
| Puff:<br>[EXPFF] | Puff 9 |
| Puff Begin:<br>[EXPFBG] | 10:04:00 |
| Puff End:<br>[EXPFEN] | 10:04:03 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |
| Row 10 | |
| Puff:<br>[EXPFF] | Puff 10 |
| Puff Begin:<br>[EXPFBG] | 10:04:30 |
| Puff End:<br>[EXPFEN] | 10:04:33 |
| Missed Puff:<br>[EXMISPF] | No |
| If yes, provide reason:<br>[EXCOM] | |

| | |
|---|---|
| Did the subject consume any beverages during controlled product use? [EXBEVB2] | No |

**AUDIT TRAIL**

VISIT: Day 6
FORM: Part B - Controlled VLN Dosing Log

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 18-Jul-2018 01:44 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Reason for change:** | Updated information | |
| **Variable** | **Old Value** | **New Value** |
| [Row 10] EXMISPF [EXMISPF] | | No |
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 28-Jun-2018 02:18 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EXDATVLN [EXDATVLN] | | 28-Jun-2018 |
| EXSTTIM [EXSTTIM] | | 10:00 |
| [Row 1] EXPFF [EXPFF] | | Puff 1 |
| [Row 1] EXPFBG [EXPFBG] | | 10:00:02 |
| [Row 1] EXPFEN [EXPFEN] | | 10:00:07 |
| [Row 1] EXMISPF [EXMISPF] | | No |
| [Row 2] EXPFF [EXPFF] | | Puff 2 |
| [Row 2] EXPFBG [EXPFBG] | | 10:00:30 |
| [Row 2] EXPFEN [EXPFEN] | | 10:00:33 |
| [Row 2] EXMISPF [EXMISPF] | | No |
| [Row 3] EXPFF | | Puff 3 |

| Variable | Old Value | New Value |
|---|---|---|
| [EXPFF] | | |
| [Row 3] EXPFBG [EXPFBG] | | 10:01:00 |
| [Row 3] EXPFEN [EXPFEN] | | 10:01:03 |
| [Row 3] EXMISPF [EXMISPF] | | No |
| [Row 4] EXPFF [EXPFF] | | Puff 4 |
| [Row 4] EXPFBG [EXPFBG] | | 10:01:30 |
| [Row 4] EXPFEN [EXPFEN] | | 10:01:33 |
| [Row 4] EXMISPF [EXMISPF] | | No |
| [Row 5] EXPFF [EXPFF] | | Puff 5 |
| [Row 5] EXPFBG [EXPFBG] | | 10:02:00 |
| [Row 5] EXPFEN [EXPFEN] | | 10:02:03 |
| [Row 5] EXMISPF [EXMISPF] | | No |
| [Row 6] EXPFF [EXPFF] | | Puff 6 |
| [Row 6] EXPFBG [EXPFBG] | | 10:02:30 |
| [Row 6] EXPFEN [EXPFEN] | | 10:02:33 |
| [Row 6] EXMISPF [EXMISPF] | | No |
| [Row 7] EXPFF [EXPFF] | | Puff 7 |
| [Row 7] EXPFBG [EXPFBG] | | 10:03:01 |
| [Row 7] EXPFEN [EXPFEN] | | 10:03:04 |
| [Row 7] EXMISPF [EXMISPF] | | No |
| [Row 8] EXPFF [EXPFF] | | Puff 8 |
| [Row 8] EXPFBG [EXPFBG] | | 10:03:30 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 8] EXPFEN [EXPFEN] | | 10:03:33 |
| [Row 8] EXMISPF [EXMISPF] | | No |
| [Row 9] EXPFF [EXPFF] | | Puff 9 |
| [Row 9] EXPFBG [EXPFBG] | | 10:04:00 |
| [Row 9] EXPFEN [EXPFEN] | | 10:04:03 |
| [Row 9] EXMISPF [EXMISPF] | | No |
| [Row 10] EXPFF [EXPFF] | | Puff 10 |
| [Row 10] EXPFBG [EXPFBG] | | 10:04:30 |
| [Row 10] EXPFEN [EXPFEN] | | 10:04:33 |
| EXBEVB2 [EXBEVB2] | | No |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Part B - Controlled VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 18-Jul-2018 01:44 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 27-Jun-2018 12:34 PM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Part B - Controlled VLN Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 02-Aug-2018 09:15 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## QUERIES

VISIT: Day 6
FORM: Part B - Controlled VLN Dosing Log

| ID | Variable | Responses/Reasons | Opened | Closed |
|---|---|---|---|---|
| | [Row 10] EXMISPF | Data Updated [18-Jul-2018 01:44 PM by (b) (6) vinceandassociates.com ((b) (6) | 28-Jun-2018 02:18 PM | 18-Jul-2018 01:44 PM |
| | **Description** | | | |
| | **New:** Missed Puff Answer is missing, please review<br>**Old:**<br>**By:** 28-Jun-2018 02:18 PM (b) (6) vinceandassociates.com ((b) (6) | | | |
| | [Row 10] EXCOM | Data Updated [18-Jul-2018 01:44 PM by (b) (6) vinceandassociates.com ((b) (6) | 28-Jun-2018 02:18 PM | 18-Jul-2018 01:44 PM |
| | **Description** | | | |
| | **New:** Comment missing, please review<br>**Old:**<br>**By:** 28-Jun-2018 02:18 PM (b) (6) vinceandassociates.com ((b) (6) | | | |

## LOCKING HISTORY

VISIT: Day 6
FORM: Part B - Controlled VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Part B - Uncontrolled VLN Dosing Log

| | |
|---|---|
| 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) | |
| Date of Visit: [EXDATB] | 28-Jun-2018 |
| Session Start Time: [EXSRTTIM] | 16:00 |
| Session End Time: [EXENDTIM] | 16:03 |
| Row 1 | |
| Inhalation Begin: [EXINHBG] | 16:00:01 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:00:03 |
| Time Unknown: [EXTIMUNK] | |
| Row 2 | |
| Inhalation Begin: [EXINHBG] | 16:00:20 |

| | |
|---|---|
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:00:22 |
| Time Unknown: [EXTIMUNK] | |
| Row 3 | |
| Inhalation Begin: [EXINHBG] | 16:00:57 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:00:59 |
| Time Unknown: [EXTIMUNK] | |
| Row 4 | |
| Inhalation Begin: [EXINHBG] | 16:01:18 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:01:20 |
| Time Unknown: [EXTIMUNK] | |
| Row 5 | |
| Inhalation Begin: [EXINHBG] | 16:01:51 |
| Time Unknown: [EXTIMUNK] | |
| Inhalation End: [EXINEN] | 16:01:53 |
| Time Unknown: [EXTIMUNK] | |

| | |
|---|---|
| Row 6 | |
| Inhalation Begin:<br>[EXINHBG] | 16:02:43 |
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | 16:02:45 |
| Time Unknown:<br>[EXTIMUNK] | |
| Row 7 | |
| Inhalation Begin:<br>[EXINHBG] | 16:03:14 |
| Time Unknown:<br>[EXTIMUNK] | |
| Inhalation End:<br>[EXINEN] | 16:03:16 |
| Time Unknown:<br>[EXTIMUNK] | |
| | |
| Did the subject consume any beverages during uncontrolled product use?<br>[EXBEVB] | No |
| Session Total Inhalations:<br>[EXINTOT] | 7 |

**AUDIT TRAIL**

VISIT: Day 6
FORM: Part B - Uncontrolled VLN Dosing Log

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 09:37 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EX9DATB<br>[EXDATB] | | 28-Jun-2018 |
| EX9SRTTIM<br>[EXSRTTIM] | | 16:00 |

| Variable | Old Value | New Value |
|---|---|---|
| EX9ENDTIM [EXENDTIM] | | 16:03 |
| [Row 1] EX9INHBG [EXINHBG] | | 16:00:01 |
| [Row 1] EX9INEN [EXINEN] | | 16:00:03 |
| [Row 2] EX9INHBG [EXINHBG] | | 16:00:20 |
| [Row 2] EX9INEN [EXINEN] | | 16:00:22 |
| [Row 3] EX9INHBG [EXINHBG] | | 16:00:57 |
| [Row 3] EX9INEN [EXINEN] | | 16:00:59 |
| [Row 4] EX9INHBG [EXINHBG] | | 16:01:18 |
| [Row 4] EX9INEN [EXINEN] | | 16:01:20 |
| [Row 5] EX9INHBG [EXINHBG] | | 16:01:51 |
| [Row 5] EX9INEN [EXINEN] | | 16:01:53 |
| [Row 6] EX9INHBG [EXINHBG] | | 16:02:43 |
| [Row 6] EX9INEN [EXINEN] | | 16:02:45 |
| [Row 7] EX9INHBG [EXINHBG] | | 16:03:14 |
| [Row 7] EX9INEN [EXINEN] | | 16:03:16 |
| EX9BEVB [EXBEVB] | | No |
| EX9INTOT [EXINTOT] | | 7 |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: Part B - Uncontrolled VLN Dosing Log

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |

| User | Date/Time | Change |
|---|---|---|
| System | 29-Jun-2018 09:37 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 27-Jun-2018 12:34 PM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 6
FORM: Part B - Uncontrolled VLN Dosing Log

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 02-Aug-2018 09:16 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Day 6
FORM: Part B - Uncontrolled VLN Dosing Log

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 6
FORM: ECG Test Results

| | |
|---|---|
| Was the ECG performed? [EGYN] | Yes |
| Date: [EGDAT] | 28-Jun-2018 |

| | |
|---|---|
| Visit:<br>[EGVIS] | Day 6 |
| Row 1 | |
| Time:<br>[EGTIM] | 19:08 |
| Time Unknown:<br>[EGTMNK] | |
| Position:<br>[EGPOS] | SUPINE |
| VR:<br>[EGVR] | 69 |
| PR Interval:<br>[EGPR] | 163 |
| QRS Interval:<br>[EGQRS] | 94 |
| QT Interval:<br>[EGQT] | 390 |
| QTcB Interval:<br>[EGQTCB] | 418 |
| QTcF:<br>[EGQTCF] | 409 |
| Clinical Significance as per MD:<br>[EGCLSIG] | NORMAL |
| If Abnormal and Clinically Significant, please specify abnormalities:<br>[EGCOM] | |

## AUDIT TRAIL

VISIT: Day 6
FORM: ECG Test Results

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 29-Jun-2018 02:57 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| EG1YN [EGYN] | | Yes |
| EG1DAT [EGDAT] | | 28-Jun-2018 |
| EGVIS [EGVIS] | | Day 6 |
| [Row 1] EG1TIM [EGTIM] | | 19:08 |
| [Row 1] EG1POS [EGPOS] | | SUPINE |
| [Row 1] EGVR [EGVR] | | 69 |
| [Row 1] EG1PR [EGPR] | | 163 |
| [Row 1] EG1QRS [EGQRS] | | 94 |
| [Row 1] EG1QT [EGQT] | | 390 |
| [Row 1] EGQTCB [EGQTCB] | | 418 |
| [Row 1] EG1QTCF [EGQTCF] | | 409 |
| [Row 1] EG1CLSIG [EGCLSIG] | | NORMAL |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: ECG Test Results

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:57 PM PDT (UTC-07:00) | Form marked as Complete |

| User | Date/Time | Change |
|---|---|---|
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 6
FORM: ECG Test Results

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**LOCKING HISTORY**

VISIT: Day 6
FORM: ECG Test Results

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Day 6
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 1st Use |
| Row 1 | |
| Time point: [QSTMPT] | |

| | |
|---|---|
| Completed:<br>[QSYN] | |

## AUDIT TRAIL

VISIT: Day 6
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF<br>[QSPERF] | | Yes |
| QSUSE<br>[QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: 1st Use - Tobacco/Nicotine Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 2nd Use |
| Row 1 | |
| Time point: [QSTMPT] | |
| Completed: [QSYN] | |

## AUDIT TRAIL

VISIT: Day 6
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| | | |
|---|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
| **Date/Time** | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF1 [QSPERF] | | Yes |

| Variable | Old Value | New Value |
|---|---|---|
| QSUSE_1 [QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: 2nd Use - Tobacco/Nicotine Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: 1st Use - Direct Effects of Product Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points:<br>[QSPERF] | Yes |
| Use:<br>[QSUSE] | 1st Use |

| Row 1 | |
|---|---|
| Time point:<br>[QSTMPT] | |
| Completed:<br>[QSYN] | |

## AUDIT TRAIL

VISIT: Day 6
FORM: 1st Use - Direct Effects of Product Questionnaire

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF_1<br>[QSPERF] | | Yes |
| QSUSE_2<br>[QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: 1st Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: 1st Use - Direct Effects of Product Questionnaire

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: 1st Use - Direct Effects of Product Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: 2nd Use - Direct Effects of Product Questionnaire

| | |
|---|---|
| Was Questionnaire performed at all time points: [QSPERF] | Yes |
| Use: [QSUSE] | 2nd Use |

| Row 1 | |
|---|---|
| Time point: [QSTMPT] | |
| Completed: [QSYN] | |

## AUDIT TRAIL

VISIT: Day 6
FORM: 2nd Use - Direct Effects of Product Questionnaire

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QSPERF2 [QSPERF] | | Yes |
| QSUSE2 [QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: 2nd Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: 2nd Use - Direct Effects of Product Questionnaire

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: 2nd Use - Direct Effects of Product Questionnaire

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: End of Study

| | |
|---|---|
| Visit Date [DSVDAT] | 28-Jun-2018 |
| Date of Completion or Discontinuation: [DSDAT] | 28-Jun-2018 |
| Date of Last Dose of Study Medication: [DSDOSDAT] | 28-Jun-2018 |
| | |
| Did the subject complete the study? [DSCOMYN] | Yes |
| If No, please mark the (b) (6) reason for discontinuation: | |
| (b) (6) reason for study discontinuation: [DSDECOD] | |
| If Other, please specify: [DSTERM] | |
| Additional Comments: [DSCOM] | |

## AUDIT TRAIL

VISIT: Day 6
FORM: End of Study

| | |
|---|---|
| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) |
| **Date/Time** | 29-Jun-2018 02:59 PM PDT (UTC-07:00) |

| Application Used | Web Browser (EDC) | |
|---|---|---|
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| DSVDAT1 [DSVDAT] | | 28-Jun-2018 |
| DSDAT [DSDAT] | | 28-Jun-2018 |
| DSDOSDT [DSDOSDAT] | | 28-Jun-2018 |
| DSCOMYN [DSCOMYN] | | Yes |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: End of Study

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 6
FORM: End of Study

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: End of Study

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: 1st Use - PK Blood Sampling

| | |
|---|---|
| Use: [PKUSE] | 1st Use (Morning Draw) |
| Row 1 | |
| Timepoint: [PKTPT] | Predose |
| Date: [PKDAT] | 28-Jun-2018 |
| Time: [PKTIM] | 09:55 |
| Not Done: [PKSTAT] | |
| Time Unknown [PKACTNK] | |
| Comments: [PKCODE] | |
| Row 2 | |
| Timepoint: [PKTPT] | 2 minute |
| Date: [PKDAT] | 28-Jun-2018 |
| Time: [PKTIM] | 10:02 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 3 | |
| Timepoint:<br>[PKTPT] | 5 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:05 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 4 | |
| Timepoint:<br>[PKTPT] | 7 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:07 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 5 | |
| Timepoint:<br>[PKTPT] | 10 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:10 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 6 | |
| Timepoint:<br>[PKTPT] | 12 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:12 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 7 | |
| Timepoint:<br>[PKTPT] | 15 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:15 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |
| Row 8 | |
| Timepoint:<br>[PKTPT] | 20 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:20 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 9 | |
| Timepoint:<br>[PKTPT] | 30 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:31 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | B - Late due to previous procedure |
| Row 10 | |
| Timepoint:<br>[PKTPT] | 45 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 10:45 |

| | |
|---|---|
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 11 | |
| Timepoint:<br>[PKTPT] | 60 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 11:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 12 | |
| Timepoint:<br>[PKTPT] | 90 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 11:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 13 | |
| Timepoint:<br>[PKTPT] | 120 minute |

| | |
|---|---|
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 12:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 14 | |
| Timepoint:<br>[PKTPT] | 150 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 12:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 15 | |
| Timepoint:<br>[PKTPT] | 180 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 13:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |

**AUDIT TRAIL**

VISIT: Day 6
FORM: 1st Use - PK Blood Sampling

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:54 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Reason for change:** | Updated information | |
| **Variable** | **Old Value** | **New Value** |
| [Row 9] PKTIM<br>[PKTIM] | | 10:31 |
| [Row 9] PKACTNK<br>[PKACTNK] | No | |
| [Row 9] PKCODE<br>[PKCODE] | | B - Late due to previous procedure |
| [Row 10] PKTIM<br>[PKTIM] | | 10:45 |
| [Row 10] PKACTNK<br>[PKACTNK] | No | |
| [Row 11] PKTIM<br>[PKTIM] | | 11:00 |
| [Row 11] PKACTNK<br>[PKACTNK] | No | |
| [Row 12] PKTIM<br>[PKTIM] | | 11:30 |
| [Row 12] PKACTNK<br>[PKACTNK] | No | |
| [Row 13] PKTIM<br>[PKTIM] | | 12:00 |
| [Row 13] PKACTNK<br>[PKACTNK] | No | |
| [Row 14] PKTIM<br>[PKTIM] | | 12:30 |
| [Row 14] PKACTNK<br>[PKACTNK] | No | |
| [Row 15] PKTIM<br>[PKTIM] | | 13:00 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 15] PKACTNK [PKACTNK] | No | |
| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
| **Date/Time** | 28-Jun-2018 09:28 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PKUSE1 [PKUSE] | | 1st Use (Morning Draw) |
| [Row 1] PKTPT [PKTPT] | | Predose |
| [Row 1] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 1] PKTIM [PKTIM] | | 09:55 |
| [Row 2] PKTPT [PKTPT] | | 2 minute |
| [Row 2] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 2] PKTIM [PKTIM] | | 10:02 |
| [Row 3] PKTPT [PKTPT] | | 5 minute |
| [Row 3] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 3] PKTIM [PKTIM] | | 10:05 |
| [Row 4] PKTPT [PKTPT] | | 7 minute |
| [Row 4] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 4] PKTIM [PKTIM] | | 10:07 |
| [Row 5] PKTPT [PKTPT] | | 10 minute |
| [Row 5] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 5] PKTIM [PKTIM] | | 10:10 |
| [Row 6] PKTPT [PKTPT] | | 12 minute |
| [Row 6] PKDAT | | 28-Jun-2018 |

| Variable | Old Value | New Value |
|---|---|---|
| [PKDAT] | | |
| [Row 6] PKTIM [PKTIM] | | 10:12 |
| [Row 7] PKTPT [PKTPT] | | 15 minute |
| [Row 7] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 7] PKTIM [PKTIM] | | 10:15 |
| [Row 8] PKTPT [PKTPT] | | 20 minute |
| [Row 8] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 8] PKTIM [PKTIM] | | 10:20 |
| [Row 9] PKTPT [PKTPT] | | 30 minute |
| [Row 9] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 9] PKACTNK [PKACTNK] | | No |
| [Row 10] PKTPT [PKTPT] | | 45 minute |
| [Row 10] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 10] PKACTNK [PKACTNK] | | No |
| [Row 11] PKTPT [PKTPT] | | 60 minute |
| [Row 11] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 11] PKACTNK [PKACTNK] | | No |
| [Row 12] PKTPT [PKTPT] | | 90 minute |
| [Row 12] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 12] PKACTNK [PKACTNK] | | No |
| [Row 13] PKTPT [PKTPT] | | 120 minute |
| [Row 13] PKDAT [PKDAT] | | 28-Jun-2018 |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 13] PKACTNK [PKACTNK] | | No |
| [Row 14] PKTPT [PKTPT] | | 150 minute |
| [Row 14] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 14] PKACTNK [PKACTNK] | | No |
| [Row 15] PKTPT [PKTPT] | | 180 minute |
| [Row 15] PKDAT [PKDAT] | | 28-Jun-2018 |
| [Row 15] PKACTNK [PKACTNK] | | No |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: 1st Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:54 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 28-Jun-2018 09:28 AM PDT (UTC-07:00) | Form marked as Not Complete |
| System | 28-Jun-2018 09:28 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: 1st Use - PK Blood Sampling

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |

| User | Date/Time | Status |
|---|---|---|
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

**QUERIES**

VISIT: Day 6
FORM: 1st Use - PK Blood Sampling

| ID | Variable | Responses/Reasons | Opened | Closed |
|---|---|---|---|---|
| | [Row 15] PKTIM | Data Updated [29-Jun-2018 02:54 PM by (b) (6) vinceandassociates.com (b) (6) | 28-Jun-2018 09:28 AM | 29-Jun-2018 02:54 PM |
| | **Description** | | | |
| | **New:** Time is missing, please review.<br>**Old:**<br>**By:** 28-Jun-2018 09:28 AM (b) (6) vinceandassociates.com (b) (6) | | | |
| | [Row 14] PKTIM | Data Updated [29-Jun-2018 02:54 PM by (b) (6) vinceandassociates.com (b) (6) | 28-Jun-2018 09:28 AM | 29-Jun-2018 02:54 PM |
| | **Description** | | | |
| | **New:** Time is missing, please review.<br>**Old:**<br>**By:** 28-Jun-2018 09:28 AM (b) (6) vinceandassociates.com (b) (6) | | | |
| | [Row 13] PKTIM | Data Updated [29-Jun-2018 02:54 PM by (b) (6) vinceandassociates.com (b) (6) | 28-Jun-2018 09:28 AM | 29-Jun-2018 02:54 PM |
| | **Description** | | | |
| | **New:** Time is missing, please review.<br>**Old:**<br>**By:** 28-Jun-2018 09:28 AM (b) (6) vinceandassociates.com (b) (6) | | | |

| ID | Variable | Responses/Reasons | Opened | Closed |
|---|---|---|---|---|
| | [Row 12] PKTIM | Data Updated [29-Jun-2018 02:54 PM by (b) (6) vinceandassociates.com ((b) (6) | 28-Jun-2018 09:28 AM | 29-Jun-2018 02:54 PM |
| | **Description** | | | |
| | **New:** Time is missing, please review.<br>**Old:**<br>**By:** 28-Jun-2018 09:28 AM (b) (6) vinceandassociates.com ((b) (6) | | | |
| | [Row 11] PKTIM | Data Updated [29-Jun-2018 02:54 PM by (b) (6) vinceandassociates.com ((b) (6) | 28-Jun-2018 09:28 AM | 29-Jun-2018 02:54 PM |
| | **Description** | | | |
| | **New:** Time is missing, please review.<br>**Old:**<br>**By:** 28-Jun-2018 09:28 AM (b) (6) vinceandassociates.com ((b) (6) | | | |
| | [Row 10] PKTIM | Data Updated [29-Jun-2018 02:54 PM by (b) (6) vinceandassociates.com ((b) (6) | 28-Jun-2018 09:28 AM | 29-Jun-2018 02:54 PM |
| | **Description** | | | |
| | **New:** Time is missing, please review.<br>**Old:**<br>**By:** 28-Jun-2018 09:28 AM (b) (6) vinceandassociates.com ((b) (6) | | | |
| | [Row 9] PKTIM | Data Updated [29-Jun-2018 02:54 PM by (b) (6) vinceandassociates.com ((b) (6) | 28-Jun-2018 09:28 AM | 29-Jun-2018 02:54 PM |
| | **Description** | | | |
| | **New:** Time is missing, please review.<br>**Old:** | | | |

| ID | Variable | Responses/Reasons | Opened | Closed |
|---|---|---|---|---|
| | **By:** 28-Jun-2018 09:28 AM (b) (6) vinceandassociates.com ((b) (6) | | | |

## LOCKING HISTORY

VISIT: Day 6
FORM: 1st Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: 2nd Use - PK Blood Sampling

| | |
|---|---|
| Use:<br>[PKUSE] | 2nd Use (Afternoon Draw) |
| Row 1 | |
| Timepoint:<br>[PKTPT] | Predose |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 15:55 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 2 | |
| Timepoint:<br>[PKTPT] | 2 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |

| | |
|---|---|
| Time:<br>[PKTIM] | 16:02 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 3 | |
| Timepoint:<br>[PKTPT] | 5 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 16:05 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 4 | |
| Timepoint:<br>[PKTPT] | 7 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 16:07 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |

| | |
|---|---|
| Row 5 | |
| Timepoint:<br>[PKTPT] | 10 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 16:10 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 6 | |
| Timepoint:<br>[PKTPT] | 12 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 16:12 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 7 | |
| Timepoint:<br>[PKTPT] | 15 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 16:15 |
| Not Done:<br>[PKSTAT] | |

| | |
|---|---|
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 8 | |
| Timepoint:<br>[PKTPT] | 20 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 16:20 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 9 | |
| Timepoint:<br>[PKTPT] | 30 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 16:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 10 | |
| Timepoint:<br>[PKTPT] | 45 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |

| | |
|---|---|
| Time:<br>[PKTIM] | 16:45 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 11 | |
| Timepoint:<br>[PKTPT] | 60 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 17:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 12 | |
| Timepoint:<br>[PKTPT] | 90 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 17:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |

| Row 13 | |
|---|---|
| Timepoint:<br>[PKTPT] | 120 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 18:00 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 14 | |
| Timepoint:<br>[PKTPT] | 150 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 18:30 |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |
| Row 15 | |
| Timepoint:<br>[PKTPT] | 180 minute |
| Date:<br>[PKDAT] | 28-Jun-2018 |
| Time:<br>[PKTIM] | 19:00 |
| Not Done:<br>[PKSTAT] | |

| | |
|---|---|
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |

**AUDIT TRAIL**

VISIT: Day 6
FORM: 2nd Use - PK Blood Sampling

| **Logged in User** | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:56 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| PKUSE<br>[PKUSE] | | 2nd Use (Afternoon Draw) |
| [Row 1] PKTPT1<br>[PKTPT] | | Predose |
| [Row 1] PKDAT1<br>[PKDAT] | | 28-Jun-2018 |
| [Row 1] PKTIM1<br>[PKTIM] | | 15:55 |
| [Row 2] PKTPT1<br>[PKTPT] | | 2 minute |
| [Row 2] PKDAT1<br>[PKDAT] | | 28-Jun-2018 |
| [Row 2] PKTIM1<br>[PKTIM] | | 16:02 |
| [Row 3] PKTPT1<br>[PKTPT] | | 5 minute |
| [Row 3] PKDAT1<br>[PKDAT] | | 28-Jun-2018 |
| [Row 3] PKTIM1<br>[PKTIM] | | 16:05 |
| [Row 4] PKTPT1<br>[PKTPT] | | 7 minute |
| [Row 4] PKDAT1<br>[PKDAT] | | 28-Jun-2018 |
| [Row 4] PKTIM1<br>[PKTIM] | | 16:07 |
| [Row 5] PKTPT1 | | 10 minute |

| Variable | Old Value | New Value |
|---|---|---|
| [PKTPT] | | |
| [Row 5] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 5] PKTIM1 [PKTIM] | | 16:10 |
| [Row 6] PKTPT1 [PKTPT] | | 12 minute |
| [Row 6] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 6] PKTIM1 [PKTIM] | | 16:12 |
| [Row 7] PKTPT1 [PKTPT] | | 15 minute |
| [Row 7] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 7] PKTIM1 [PKTIM] | | 16:15 |
| [Row 8] PKTPT1 [PKTPT] | | 20 minute |
| [Row 8] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 8] PKTIM1 [PKTIM] | | 16:20 |
| [Row 9] PKTPT1 [PKTPT] | | 30 minute |
| [Row 9] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 9] PKTIM1 [PKTIM] | | 16:30 |
| [Row 10] PKTPT1 [PKTPT] | | 45 minute |
| [Row 10] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 10] PKTIM1 [PKTIM] | | 16:45 |
| [Row 11] PKTPT1 [PKTPT] | | 60 minute |
| [Row 11] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 11] PKTIM1 [PKTIM] | | 17:00 |
| [Row 12] PKTPT1 [PKTPT] | | 90 minute |

| Variable | Old Value | New Value |
|---|---|---|
| [Row 12] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 12] PKTIM1 [PKTIM] | | 17:30 |
| [Row 13] PKTPT1 [PKTPT] | | 120 minute |
| [Row 13] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 13] PKTIM1 [PKTIM] | | 18:00 |
| [Row 14] PKTPT1 [PKTPT] | | 150 minute |
| [Row 14] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 14] PKTIM1 [PKTIM] | | 18:30 |
| [Row 15] PKTPT1 [PKTPT] | | 180 minute |
| [Row 15] PKDAT1 [PKDAT] | | 28-Jun-2018 |
| [Row 15] PKTIM1 [PKTIM] | | 19:00 |

**FORM STATUS CHANGE LOG**

VISIT: Day 6
FORM: 2nd Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:56 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**FORM APPROVAL**

VISIT: Day 6
FORM: 2nd Use - PK Blood Sampling

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |

| User | Date/Time | Status |
|---|---|---|
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: 2nd Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Use Product Again - VAS 1st use

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |
| Use: [QSUSE] | 1st Use |

## AUDIT TRAIL

VISIT: Day 6
FORM: Use Product Again - VAS 1st use

| Logged in User | (b) (6) vinceandassociates.com ((b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF [QSPERF] | | Yes |
| QS5USE [QSUSE] | | 1st Use |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Use Product Again - VAS 1st use

| User | Date/Time | Change |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Use Product Again - VAS 1st use

| User | Date/Time | Status |
|---|---|---|
| (b) (6) algopharm.com ((b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com ((b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: Use Product Again - VAS 1st use

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Day 6
FORM: Use Product Again - VAS 2nd use

| | |
|---|---|
| Was Questionnaire performed? [QSPERF] | Yes |

| | |
|---|---|
| Use:<br>[QSUSE] | 2nd Use |

## AUDIT TRAIL

VISIT: Day 6
FORM: Use Product Again - VAS 2nd use

| **Logged in User** | (b) (6) vinceandassociates.com (b) (6) | |
|---|---|---|
| **Date/Time** | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| QS5PERF<br>[QSPERF] | | Yes |
| QS5USE<br>[QSUSE] | | 2nd Use |

## FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Use Product Again - VAS 2nd use

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 29-Jun-2018 02:59 PM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: Day 6
FORM: Use Product Again - VAS 2nd use

| **User** | **Date/Time** | **Status** |
|---|---|---|
| (b) (6) algopharm.com (b) (6) (b) (6) | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| (b) (6) gmail.com (b) (6) (b) (6) | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: Day 6
FORM: Use Product Again - VAS 2nd use

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Early Term
FORM: Visit Date

| | |
|---|---|
| Visit Done? [SVYN] | |
| Date of Visit: [SVSTDAT] | |

## FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Visit Date

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Early Term
FORM: Visit Date

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Early Term
FORM: Vital Signs

| | |
|---|---|
| Visit:<br>[VSVIS] | |
| Were vital signs measured?<br>[VSPERF] | |
| Repeat vital signs?<br>[VSPERFR] | |
| Time Seated:<br>[VS1TIMS] | |
| Time Seated Unknown:<br>[VSTIMSUN] | |
| Date:<br>[VSDAT] | |
| Time Taken:<br>[VSTIM] | |
| Time Unknown:<br>[VSTMNK] | |

| Row 1 | |
|---|---|
| Assessment:<br>[VSTEST] | |
| Not done:<br>[VSSTAT] | |
| Result:<br>[VSORRES] | |
| Unit:<br>[VSORRESU] | |
| MD Safety Review:<br>[VSCLSIG] | |

## FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Vital Signs

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Early Term
FORM: Vital Signs

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

| | |
|---|---|
| Visit: [LBVIS] | |
| Was the laboratory evaluation performed? [LBYN] | |
| Date of collection: [LBDAT] | |
| Time of Collection: [LBTIM] | |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | |
| Row 1 | |
| Test Name: [LBTEST] | |

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

## FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Early Term
FORM: Hematology Laboratory Evaluation

| | |
|---|---|
| Visit: [LBVIS] | |
| Was the laboratory evaluation performed? [LBYN] | |
| Date of collection: [LBDAT] | |
| Time of Collection: [LBTIM] | |
| Time Unknown: [LBTMNK] | |
| Are all results within normal limits? [LBNRIND] | |

| Row 1 | |
|---|---|
| Test Name:<br>[LBTEST] | |
| Clinical Significance as per MD: (Please record an AE for Clinically Significant results)<br>[LBCLSIG] | |

**FORM STATUS CHANGE LOG**

VISIT: Early Term
FORM: Hematology Laboratory Evaluation

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Early Term
FORM: Hematology Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Early Term
FORM: Urinalysis Laboratory Evaluation

| | |
|---|---|
| Visit:<br>[LBVIS] | |
| Was the laboratory evaluation performed?<br>[LBYN] | |
| Date of collection:<br>[LBDAT] | |
| Time of Collection:<br>[LBTIM] | |

| | |
|---|---|
| Time Unknown:<br>[LBTMNK] | |
| Are all results within normal limits?<br>[LBNRIND] | |

| Row 1 | |
|---|---|
| Test Name:<br>[LBTEST] | |
| Clinical Significance as per MD: (Please record an AE for Clinically Significant results)<br>[LBCLSIG] | |

**FORM STATUS CHANGE LOG**

VISIT: Early Term
FORM: Urinalysis Laboratory Evaluation

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Early Term
FORM: Urinalysis Laboratory Evaluation

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Early Term
FORM: Symptom Directed Physical Exam

| | |
|---|---|
| Visit:<br>[PEVIS] | |
| Was physical examination performed?<br>[PEYN] | |

| | |
|---|---|
| Examination Date:<br>[PEDAT] | |
| Completion Time:<br>[PTIM] | |
| ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM | |

| Row 1 | |
|---|---|
| Body System Examined:<br>[PETEST] | |
| Not done:<br>[PESTAT] | |
| Examination Results:<br>[PEORRES] | |
| Abnormal Findings:<br>[PECLSIG] | |

| | |
|---|---|
| If Other, please specify:<br>[PEOTHSP] | |

**FORM STATUS CHANGE LOG**

VISIT: Early Term
FORM: Symptom Directed Physical Exam

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

**LOCKING HISTORY**

VISIT: Early Term
FORM: Symptom Directed Physical Exam

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

**CLINICAL DATA**

VISIT: Early Term
FORM: ECG Test Results

| | |
|---|---|
| Was the ECG performed?<br>[EGYN] | |
| Date:<br>[EGDAT] | |
| Visit:<br>[EGVIS] | |
| Row 1 | |
| Time:<br>[EGTIM] | |
| Time Unknown:<br>[EGTMNK] | |
| Position:<br>[EGPOS] | |
| VR:<br>[EGVR] | |
| PR Interval:<br>[EGPR] | |
| QRS Interval:<br>[EGQRS] | |
| QT Interval:<br>[EGQT] | |
| QTcB Interval:<br>[EGQTCB] | |
| QTcF:<br>[EGQTCF] | |
| Clinical Significance as per MD:<br>[EGCLSIG] | |
| If Abnormal and Clinically Significant, please specify abnormalities:<br>[EGCOM] | |

## FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: ECG Test Results

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Early Term
FORM: ECG Test Results

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Early Term
FORM: End of Study

| | |
|---|---|
| Visit Date [DSVDAT] | |
| Date of Completion or Discontinuation: [DSDAT] | |
| Date of Last Dose of Study Medication: [DSDOSDAT] | |
| | |
| Did the subject complete the study? [DSCOMYN] | |
| If No, please mark the (b) (6) reason for discontinuation: | |
| (b) (6) reason for study discontinuation: [DSDECOD] | |
| If Other, please specify: [DSTERM] | |

| | |
|---|---|
| Additional Comments:<br>[DSCOM] | |

## FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: End of Study

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com<br>((b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Early Term
FORM: End of Study

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com<br>((b) (6)<br>(b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Early Term
FORM: 1st Use - PK Blood Sampling

| | |
|---|---|
| Use:<br>[PKUSE] | |
| Row 1 | |
| Timepoint:<br>[PKTPT] | |
| Date:<br>[PKDAT] | |
| Time:<br>[PKTIM] | |
| Not Done:<br>[PKSTAT] | |
| Time Unknown<br>[PKACTNK] | |

| | |
|---|---|
| Comments:<br>[PKCODE] | |

## FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: 1st Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com (b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Early Term
FORM: 1st Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com (b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: Early Term
FORM: 2nd Use - PK Blood Sampling

| | |
|---|---|
| Use:<br>[PKUSE] | |
| Row 1 | |
| Timepoint:<br>[PKTPT] | |
| Date:<br>[PKDAT] | |
| Time:<br>[PKTIM] | |
| Not Done:<br>[PKSTAT] | |

| | |
|---|---|
| Time Unknown<br>[PKACTNK] | |
| Comments:<br>[PKCODE] | |

## FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: 2nd Use - PK Blood Sampling

| User | Date/Time | Change |
|---|---|---|
| (b) (6) vinceandassociates.com ((b) (6) | 29-Jun-2018 01:40 PM PDT (UTC-07:00) | Form marked as Not Expected |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## LOCKING HISTORY

VISIT: Early Term
FORM: 2nd Use - PK Blood Sampling

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: All Visits
FORM: Adverse Events

| | |
|---|---|
| Were any Adverse Events experienced?<br>[AEYN] | No |
| Row 1 | |
| AE Identifier:<br>[AESPID] | |
| Adverse Event Term:<br>[AETERM] | |
| Is this an SAE?<br>[AESER] | |

| | |
|---|---|
| Severity:<br>[AESEV] | |
| Frequency:<br>[AEFREQ] | |
| Action Taken with Study Treatment:<br>[AEACN] | |
| Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form)<br>[AECONTRT] | |
| Did the AE result in withdrawal from study?<br>[AEDIS] | |
| Relationship to Investigational Product:<br>[AEREL] | |
| Was this AE a result of Study Medication error?<br>[AETEAE] | |
| Outcome:<br>[AEOUT] | |
| Onset Date:<br>[AESTDAT] | |
| Onset Time:<br>[AESTTIM] | |
| Time Unknown:<br>[AESTTMNK] | |
| AE Ongoing?<br>[AEONGO] | |
| End Date:<br>[AEENDAT] | |
| End Time:<br>[AEENTIM] | |
| Time Unknown:<br>[AEENTMNK] | |

## AUDIT TRAIL

VISIT: All Visits
FORM: Adverse Events

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 03-Jul-2018 10:09 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| AEYN<br>[AEYN] | | No |

## FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Adverse Events

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 03-Jul-2018 10:09 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: All Visits
FORM: Adverse Events

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] algopharm.com ([redacted] [redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] [redacted] | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: All Visits
FORM: Adverse Events

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algopharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |

## CLINICAL DATA

VISIT: All Visits
FORM: Concomitant Medications

| | |
|---|---|
| Were there any medications the subject has taken in the past 30 days and throughout the study? [CMYN] | No |
| Row 1 | |
| CM Number: [CMNUM] | |
| Medication/Therapy/Procedure: [CMTRT] | |
| Indication: [CMINDC] | |
| If Other, please specify: [CMINDOT] | |
| Adverse Event #: [CMAENUM] | |
| Medical History #: [CMMHNUM] | |
| Strength: [CMDOSE] | |
| Unit: [CMDOSU] | |
| If Other, please specify: [CMDOSOTH] | |

| | |
|---|---|
| Quantity:<br>[CMQUANT] | |
| Form:<br>[CMDOSFRM] | |
| If Other, please specify:<br>[CMFRMOT] | |
| Total Dose:<br>[CMTOTDOS] | |
| Unit:<br>[CMTOTUN] | |
| If Other, please specify:<br>[CMUNOT] | |
| Route:<br>[CMROUTE] | |
| If other, please specify:<br>[CMOTHER] | |
| Frequency:<br>[CMDOSFRQ] | |
| If Other, please specify:<br>[CMFRQOT] | |
| Start Date:<br>[CMSTDAT] | |
| Start Time:<br>[CMSTTIM] | |
| Time Unknown<br>[CMSTTNK] | |
| End Date:<br>[CMENDAT] | |
| End Time:<br>[CMENTIM] | |
| Time Unknown<br>[CMENTNK] | |
| Ongoing?<br>[CMONGO] | |

## AUDIT TRAIL

VISIT: All Visits
FORM: Concomitant Medications

| **Logged in User** | [redacted] vinceandassociates.com ([redacted] | |
|---|---|---|
| **Date/Time** | 03-Jul-2018 10:09 AM PDT (UTC-07:00) | |
| **Application Used** | Web Browser (EDC) | |
| **Subject Entry** | No | |
| **Variable** | **Old Value** | **New Value** |
| CMYN<br>[CMYN] | | No |

## FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Concomitant Medications

| **User** | **Date/Time** | **Change** |
|---|---|---|
| System | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Form marked as Complete Final |
| System | 03-Jul-2018 10:09 AM PDT (UTC-07:00) | Form marked as Complete |
| System | 25-Jun-2018 08:08 AM PDT (UTC-07:00) | Form marked as Not Complete |

## FORM APPROVAL

VISIT: All Visits
FORM: Concomitant Medications

| **User** | **Date/Time** | **Status** |
|---|---|---|
| [redacted] gmail.com ([redacted] | 25-Oct-2018 11:23 AM PDT (UTC-07:00) | Form marked as "Form Monitored". |
| [redacted] algopharm.com ([redacted] | 11-Oct-2018 02:30 PM PDT (UTC-07:00) | Updated information ( Form unmarked as "Form Monitored" ). - ESignature |
| [redacted] algopharm.com ([redacted] | 04-Oct-2018 05:56 AM PDT (UTC-07:00) | Form marked as "Freeze". |
| dkelsh (Debra Kelsh) | 04-Oct-2018 05:33 AM PDT (UTC-07:00) | Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature |
| [redacted] gmail.com ([redacted] | 06-Aug-2018 02:33 PM PDT (UTC-07:00) | Form marked as "Form Monitored". |

## LOCKING HISTORY

VISIT: All Visits
FORM: Concomitant Medications

| Item type | Item | Row Number | User | Date/Time | Old Value | New Value |
|---|---|---|---|---|---|---|
| Form | | | (b) (6) algo pharm.com ((b) (6) (b) (6) | 26-Oct-2018 01:27 PM PDT (UTC-07:00) | Unlocked | Locked |