Table of Contents

01-112 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 25
  - Medical History 26
    - Data 26
    - Audit Trail 29
  - Complete Physical Examination 32
    - Data 32
    - Audit Trail 36
  - Height, Weight and BMI 38
    - Data 38
    - Audit Trail 39
  - Serology Lab Evaluation 40
    - Data 40
    - Audit Trail 41
  - Serum Pregnancy Test 42
    - Data 42
  - Vital Signs 43
    - Data 43
    - Audit Trail 45
  - UDS and Alcohol Laboratory Evaluation 47
    - Data 47
    - Audit Trail 48
  - Cotinine Evaluation 49
    - Data 49
    - Audit Trail 50
  - Chemistry Laboratory Evaluation 51
    - Data 51
    - Audit Trail 52
  - Hematology Laboratory Evaluation 53
    - Data 53

Audit Trail 54
Urinalysis Laboratory Evaluation 55
Data 55
Audit Trail 56
Endocrinology Evaluation 57
Data 57
ECG Test Results 58
Data 58
Audit Trail 59
Female Contraceptive Method 61
Data 61
Tobacco Use 62
Data 62
Audit Trail 66
Query Log 68
Day -1 69
Visit Date 69
Data 69
Audit Trail 70
Urine Pregnancy Test 71
Data 71
Vital Signs 72
Data 72
Audit Trail 74
UDS and Alcohol Laboratory Evaluation 76
Data 76
Audit Trail 77
Symptom Directed Physical Exam 78
Data 78
Audit Trail 79
Day 1 80
Visit Date 80
Data 80
Audit Trail 81
Part A - Usual Brand Dose Log 82
Data 82
Part A - VLN Dosing Log 83
Data 83
Audit Trail 86
Part A - Nicorette Dosing Log 89
Data 89
Randomization 90
Data 90

Audit Trail 90
Query Log 91
Use Product Again - VAS 92
Data 92
Audit Trail 92
Day 2 93
Visit Date 93
Data 93
Audit Trail 94
Part A - Usual Brand Dose Log 95
Data 95
Audit Trail 98
Part A - VLN Dosing Log 101
Data 101
Part A - Nicorette Dosing Log 102
Data 102
Use Product Again - VAS 103
Data 103
Audit Trail 103
Day 3 104
Visit Date 104
Data 104
Audit Trail 105
Part A - Usual Brand Dose Log 106
Data 106
Part A - VLN Dosing Log 107
Data 107
Part A - Nicorette Dosing Log 108
Data 108
Audit Trail 110
Use Product Again - VAS 112
Data 112
Audit Trail 112
Day 4 114
Visit Date 114
Data 114
Audit Trail 114
Randomization 115
Data 115
Audit Trail 115
Part B - Controlled Nicorette Dosing Log-1 117
Data 117
Part B - Uncontrolled Nicorette Dosing Log 118

Data 118
Part B - Uncontrolled Usual Brand Dosing Log 119
Data 119
Part B - Controlled Usual Brand Dosing Log 120
Data 120
Part B - Controlled VLN Dosing Log 121
Data 121
Audit Trail 125
Part B - Uncontrolled VLN Dosing Log 128
Data 128
Audit Trail 132
1st Use - Tobacco/Nicotine Questionnaire 134
Data 134
Audit Trail 135
2nd Use - Tobacco/Nicotine Questionnaire 136
Data 136
Audit Trail 136
1st Use - Direct Effects of Product Questionnaire 137
Data 137
Audit Trail 138
2nd Use - Direct Effects of Product Questionnaire 139
Data 139
Audit Trail 140
1st Use - PK Blood Sampling 141
Data 141
Audit Trail 147
2nd Use - PK Blood Sampling 150
Data 150
Audit Trail 156
Use Product Again - VAS 1st use 160
Data 160
Audit Trail 160
Use Product Again - VAS 2nd use 161
Data 161
Audit Trail 161
Day 5 162
Visit Date 162
Data 162
Audit Trail 163
Part B - Controlled Nicorette Dosing Log 164
Data 164
Part B - Uncontrolled Nicorette Dosing Log 165
Data 165

Part B - Uncontrolled Usual Brand Dosing Log 166
Data 166
Audit Trail 170
Query Log 173
Part B - Controlled Usual Brand Dosing Log 174
Data 174
Audit Trail 177
Part B - Controlled VLN Dosing Log 181
Data 181
Part B - Uncontrolled VLN Dosing Log 182
Data 182
1st Use - Tobacco/Nicotine Questionnaire 183
Data 183
Audit Trail 184
2nd Use - Tobacco/Nicotine Questionnaire 185
Data 185
Audit Trail 185
1st Use - Direct Effects of Product Questionnaire 186
Data 186
Audit Trail 187
2nd Use - Direct Effects of Product Questionnaire 188
Data 188
Audit Trail 189
1st Use - PK Blood Sampling 190
Data 190
Audit Trail 196
2nd Use - PK Blood Sampling 199
Data 199
Audit Trail 205
Use Product Again - VAS 1st use 208
Data 208
Audit Trail 209
Use Product Again - VAS 2nd use 210
Data 210
Audit Trail 210
Day 6 211
Visit Date 211
Data 211
Audit Trail 212
Vital Signs 213
Data 213
Audit Trail 215
Chemistry Laboratory Evaluation 217

Data 217
Audit Trail 218
Hematology Laboratory Evaluation 219
Data 219
Audit Trail 220
Urinalysis Laboratory Evaluation 221
Data 221
Audit Trail 222
Symptom Directed Physical Exam 223
Data 223
Audit Trail 224
Part B - Controlled Nicorette Dosing Log-1 225
Data 225
Audit Trail 226
Part B - Uncontrolled Nicorette Dosing Log 227
Data 227
Audit Trail 228
Part B - Controlled Usual Brand Dosing Log 229
Data 229
Part B - Uncontrolled Usual Brand Dosing Log 231
Data 231
Part B - Controlled VLN Dosing Log 232
Data 232
Part B - Uncontrolled VLN Dosing Log 233
Data 233
ECG Test Results 235
Data 235
Audit Trail 236
1st Use - Tobacco/Nicotine Questionnaire 237
Data 237
Audit Trail 238
2nd Use - Tobacco/Nicotine Questionnaire 239
Data 239
Audit Trail 239
1st Use - Direct Effects of Product Questionnaire 241
Data 241
Audit Trail 241
2nd Use - Direct Effects of Product Questionnaire 242
Data 242
Audit Trail 243
End of Study 244
Data 244
Audit Trail 244

1st Use - PK Blood Sampling 246
Data 246
Audit Trail 252
Query Log 256
2nd Use - PK Blood Sampling 258
Data 258
Audit Trail 264
Use Product Again - VAS 1st use 267
Data 267
Audit Trail 268
Use Product Again - VAS 2nd use 269
Data 269
Audit Trail 269
Early Term 270
Visit Date 270
Data 270
Vital Signs 271
Data 271
Chemistry Laboratory Evaluation 272
Data 272
Hematology Laboratory Evaluation 274
Data 274
Urinalysis Laboratory Evaluation 275
Data 275
Symptom Directed Physical Exam 276
Data 276
ECG Test Results 277
Data 277
End of Study 279
Data 279
1st Use - PK Blood Sampling 280
Data 280
2nd Use - PK Blood Sampling 281
Data 281
All Visits 282
Adverse Events 282
Data 282
Audit Trail 286
Query Log 290
Concomitant Medications 290
Data 290
Audit Trail 292

By Domain

Table of Contents

Visit Date 19
Screening 19
Data 19
Audit Trail 19
Day -1 69
Data 69
Audit Trail 70
Day 1 80
Data 80
Audit Trail 81
Day 2 93
Data 93
Audit Trail 94
Day 3 104
Data 104
Audit Trail 105
Day 4 114
Data 114
Audit Trail 114
Day 5 162
Data 162
Audit Trail 163
Day 6 211
Data 211
Audit Trail 212
Early Term 270
Data 270
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 25
Medical History 26
Screening 19
Data 26
Audit Trail 29

Table of Contents

Complete Physical Examination 32
Screening 19
Data 32
Audit Trail 36
Height, Weight and BMI 38
Screening 19
Data 38
Audit Trail 39
Serology Lab Evaluation 40
Screening 19
Data 40
Audit Trail 41
Serum Pregnancy Test 42
Screening 19
Data 42
Vital Signs 43
Screening 19
Data 43
Audit Trail 45
Day -1 69
Data 72
Audit Trail 74
Day 6 211
Data 213
Audit Trail 215
Early Term 270
Data 271
UDS and Alcohol Laboratory Evaluation 47
Screening 19
Data 47
Audit Trail 48
Day -1 69
Data 76
Audit Trail 77
Cotinine Evaluation 49
Screening 19
Data 49
Audit Trail 50
Chemistry Laboratory Evaluation 51
Screening 19
Data 51
Audit Trail 52
Day 6 211

Data 217
Audit Trail 218
Early Term 270
Data 272
Hematology Laboratory Evaluation 53
Screening 19
Data 53
Audit Trail 54
Day 6 211
Data 219
Audit Trail 220
Early Term 270
Data 274
Urinalysis Laboratory Evaluation 55
Screening 19
Data 55
Audit Trail 56
Day 6 211
Data 221
Audit Trail 222
Early Term 270
Data 275
Endocrinology Evaluation 57
Screening 19
Data 57
ECG Test Results 58
Screening 19
Data 58
Audit Trail 59
Day 6 211
Data 235
Audit Trail 236
Early Term 270
Data 277
Female Contraceptive Method 61
Screening 19
Data 61
Tobacco Use 62
Screening 19
Data 62
Audit Trail 66
Query Log 68
Urine Pregnancy Test 71

Day -1 69
Data 71
Symptom Directed Physical Exam 78
Day -1 69
Data 78
Audit Trail 79
Day 6 211
Data 223
Audit Trail 224
Early Term 270
Data 276
Part A - Usual Brand Dose Log 82
Day 1 80
Data 82
Day 2 93
Data 95
Audit Trail 98
Day 3 104
Data 106
Part A - VLN Dosing Log 83
Day 1 80
Data 83
Audit Trail 86
Day 2 93
Data 101
Day 3 104
Data 107
Part A - Nicorette Dosing Log 89
Day 1 80
Data 89
Day 2 93
Data 102
Day 3 104
Data 108
Audit Trail 110
Randomization 90
Day 1 80
Data 90
Audit Trail 90
Query Log 91
Day 4 114
Data 115
Audit Trail 115

Table of Contents

Use Product Again - VAS 92
Day 1 80
Data 92
Audit Trail 92
Day 2 93
Data 103
Audit Trail 103
Day 3 104
Data 112
Audit Trail 112
Part B - Controlled Nicorette Dosing Log-1 117
Day 4 114
Data 117
Day 6 211
Data 225
Audit Trail 226
Part B - Uncontrolled Nicorette Dosing Log 118
Day 4 114
Data 118
Day 5 162
Data 165
Day 6 211
Data 227
Audit Trail 228
Part B - Uncontrolled Usual Brand Dosing Log 119
Day 4 114
Data 119
Day 5 162
Data 166
Audit Trail 170
Query Log 173
Day 6 211
Data 231
Part B - Controlled Usual Brand Dosing Log 120
Day 4 114
Data 120
Day 5 162
Data 174
Audit Trail 177
Day 6 211
Data 229
Part B - Controlled VLN Dosing Log 121
Day 4 114

Data 121
Audit Trail 125
Day 5 162
Data 181
Day 6 211
Data 232
Part B - Uncontrolled VLN Dosing Log 128
Day 4 114
Data 128
Audit Trail 132
Day 5 162
Data 182
Day 6 211
Data 233
1st Use - Tobacco/Nicotine Questionnaire 134
Day 4 114
Data 134
Audit Trail 135
Day 5 162
Data 183
Audit Trail 184
Day 6 211
Data 237
Audit Trail 238
2nd Use - Tobacco/Nicotine Questionnaire 136
Day 4 114
Data 136
Audit Trail 136
Day 5 162
Data 185
Audit Trail 185
Day 6 211
Data 239
Audit Trail 239
1st Use - Direct Effects of Product Questionnaire 137
Day 4 114
Data 137
Audit Trail 138
Day 5 162
Data 186
Audit Trail 187
Day 6 211
Data 241

Audit Trail 241
2nd Use - Direct Effects of Product Questionnaire 139
Day 4 114
Data 139
Audit Trail 140
Day 5 162
Data 188
Audit Trail 189
Day 6 211
Data 242
Audit Trail 243
1st Use - PK Blood Sampling 141
Day 4 114
Data 141
Audit Trail 147
Day 5 162
Data 190
Audit Trail 196
Day 6 211
Data 246
Audit Trail 252
Query Log 256
Early Term 270
Data 280
2nd Use - PK Blood Sampling 150
Day 4 114
Data 150
Audit Trail 156
Day 5 162
Data 199
Audit Trail 205
Day 6 211
Data 258
Audit Trail 264
Early Term 270
Data 281
Use Product Again - VAS 1st use 160
Day 4 114
Data 160
Audit Trail 160
Day 5 162
Data 208
Audit Trail 209

Day 6 211
Data 267
Audit Trail 268
Use Product Again - VAS 2nd use 161
Day 4 114
Data 161
Audit Trail 161
Day 5 162
Data 210
Audit Trail 210
Day 6 211
Data 269
Audit Trail 269
Part B - Controlled Nicorette Dosing Log 164
Day 5 162
Data 164
End of Study 244
Day 6 211
Data 244
Audit Trail 244
Early Term 270
Data 279
Adverse Events 282
All Visits 282
Data 282
Audit Trail 286
Query Log 290
Concomitant Medications 290
All Visits 282
Data 290
Audit Trail 292

Site:	Site A
Group:	Group A
Medrio ID:	0038
Subject Identifier:	01-112
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 08:50 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		01-112
Medrio ID	25-Jun-2018 08:50 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		38
Subject Status	25-Jun-2018 08:50 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Enrolled
Site	25-Jun-2018 08:50 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Site A
Group	25-Jun-2018 08:50 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Group A
ePRO Enabled	25-Jun-2018 08:50 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)
All Visits	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)

CLINICAL DATA

VISIT: Screening
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	08-Jun-2018

AUDIT TRAIL

VISIT: Screening
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 08:58 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		08-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 08:58 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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]	08-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 08:58 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]		08-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 08:58 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	25-Jun-2018 08:59 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
IEYN [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 08:59 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

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)	07-Aug-2018 02:04 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]	08-Jun-2018
Date of Birth: [DMBRTHDAT]	(b) (6)
Age: [DMAGE]	47
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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	25-Jun-2018 08:59 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DMDAT [DMDAT]		08-Jun-2018
DMBRTHDAT [DMBRTHDAT]		[redacted]
DMAGE [DMAGE]		47
DMAGEU [DMAGEU]		YEARS
DMSEX [DMSEX]		M
DMETHNIC [DMETHNIC]		NOT 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
System	25-Jun-2018 08:59 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Demographics

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)	07-Aug-2018 02:04 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) algo pharm.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: [MHDAT]	08-Jun-2018
Row 1	
Medical History #: [MHNUM]	1
Body System Code: [MHSCAT]	Immunologic/Allergies
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	ALLERGIC TO NOVOCAINE - HIVES
Onset Date: [MHSTDAT]	UN-UNK-1983

Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	Yes
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 2	
Medical History #: [MHNUM]	2
Body System Code: [MHSCAT]	Musculoskeletal
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	BULGING DISK L4-L5
Onset Date: [MHSTDAT]	UN-UNK-2010
Date Resolved: [MHENDAT]	UN-UNK-2012
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 3	
Medical History #: [MHNUM]	3
Body System Code: [MHSCAT]	Surgical
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	DISCECTOMY L4-L5
Onset Date: [MHSTDAT]	UN-UNK-2010

Date Resolved: [MHENDAT]	UN-UNK-2010
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 4	
Medical History #: [MHNUM]	4
Body System Code: [MHSCAT]	Surgical
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	DISCECTOMY L4-L5 (SECOND SURGERY)
Onset Date: [MHSTDAT]	UN-UNK-2012
Date Resolved: [MHENDAT]	UN-UNK-2012
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 5	
Medical History #: [MHNUM]	5
Body System Code: [MHSCAT]	Musculoskeletal
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	TENDON RUPTURE - RIGHT BICEP
Onset Date: [MHSTDAT]	UN-UNK-2011

Date Resolved: [MHENDAT]	UN-UNK-2011
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 6	
Medical History #: [MHNUM]	6
Body System Code: [MHSCAT]	Surgical
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	REPAIR OF TENDON - RIGHT BICEP
Onset Date: [MHSTDAT]	UN-UNK-2011
Date Resolved: [MHENDAT]	UN-UNK-2011
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant

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

AUDIT TRAIL

VISIT: Screening
FORM: Medical History

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	25-Jun-2018 09:44 AM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
MHYN [MHYN]		Yes
MHDAT [MHDAT]		08-Jun-2018
[Row 1] MHNUM [MHNUM]		1
[Row 1] MHSCAT [MHSCAT]		Immunologic/Allergies
[Row 1] MHCAT [MHSCAT]		ALLERGIC TO NOVOCAINE - HIVES
[Row 1] MHSTDAT [MHSTDAT]		UN-UNK-1983
[Row 1] MHONGO [MHONGO]		Yes
[Row 1] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 2] MHNUM [MHNUM]		2
[Row 2] MHSCAT [MHSCAT]		Musculoskeletal
[Row 2] MHCAT [MHSCAT]		BULGING DISK L4-L5
[Row 2] MHSTDAT [MHSTDAT]		UN-UNK-2010
[Row 2] MHENDAT [MHENDAT]		UN-UNK-2012
[Row 2] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 3] MHNUM [MHNUM]		3
[Row 3] MHSCAT [MHSCAT]		Surgical
[Row 3] MHCAT [MHSCAT]		DISCECTOMY L4-L5
[Row 3] MHSTDAT [MHSTDAT]		UN-UNK-2010
[Row 3] MHENDAT [MHENDAT]		UN-UNK-2010
[Row 3] MHCLSIG [MHCLSIG]		Not Clinically Sigficant

Variable	Old Value	New Value
[Row 4] MHNUM [MHNUM]		4
[Row 4] MHSCAT [MHSCAT]		Surgical
[Row 4] MHCAT [MHSCAT]		DISCECTOMY L4-L5 (SECOND SURGERY)
[Row 4] MHSTDAT [MHSTDAT]		UN-UNK-2012
[Row 4] MHENDAT [MHENDAT]		UN-UNK-2012
[Row 4] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 5] MHNUM [MHNUM]		5
[Row 5] MHSCAT [MHSCAT]		Musculoskeletal
[Row 5] MHCAT [MHSCAT]		TENDON RUPTURE - RIGHT BICEP
[Row 5] MHSTDAT [MHSTDAT]		UN-UNK-2011
[Row 5] MHENDAT [MHENDAT]		UN-UNK-2011
[Row 5] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 6] MHNUM [MHNUM]		6
[Row 6] MHSCAT [MHSCAT]		Surgical
[Row 6] MHCAT [MHSCAT]		REPAIR OF TENDON - RIGHT BICEP
[Row 6] MHSTDAT [MHSTDAT]		UN-UNK-2011
[Row 6] MHENDAT [MHENDAT]		UN-UNK-2011
[Row 6] 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 09:44 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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) algopharm.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]	08-Jun-2018
Completion Time: [PETIM]	11:10
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: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 3	
Body System Examined: [PETEST]	NECK/THYROID
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	

Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 4	
Body System Examined: [PETEST]	CARDIOVASCULAR
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 5	
Body System Examined: [PETEST]	RESPIRATORY
Not done: [PESTAT]	
If Other, please specify: [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 09:45 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN [PEYN]		Yes
PEDAT [PEDAT]		08-Jun-2018
PETIM [PETIM]		11:10
[Row 1] PETEST [PETEST]		GENERAL APPEARANCE
[Row 1] PEORRES [PEORRES]		NORMAL
[Row 2] PETEST [PETEST]		HEENT
[Row 2] PEORRES [PEORRES]		NORMAL
[Row 3] PETEST [PETEST]		NECK/THYROID
[Row 3] PEORRES [PEORRES]		NORMAL

Variable	Old Value	New Value
[Row 4] PETEST [PETEST]		CARDIOVASCULAR
[Row 4] PEORRES [PEORRES]		NORMAL
[Row 5] PETEST [PETEST]		RESPIRATORY
[Row 5] PEORRES [PEORRES]		NORMAL
[Row 6] PETEST [PETEST]		GASTROINTESTINAL
[Row 6] PEORRES [PEORRES]		NORMAL
[Row 7] PETEST [PETEST]		NEUROLOGICAL
[Row 7] PEORRES [PEORRES]		NORMAL
[Row 8] PETEST [PETEST]		MUSCULOSKELETAL/EXTREMITIES
[Row 8] PEORRES [PEORRES]		NORMAL
[Row 9] PETEST [PETEST]		SKIN
[Row 9] PEORRES [PEORRES]		NORMAL
[Row 10] PETEST [PETEST]		OTHER
[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 09:45 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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? [VSYN]	Yes
Visit Date: [VSDAT]	08-Jun-2018
Height: [VSHGT]	172.0
Weight: [VSWGT]	70.2
BMI: [VSBMI]	23.7

AUDIT TRAIL

VISIT: Screening
FORM: Height, Weight and BMI

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	25-Jun-2018 09:00 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSYN [VSYN]		Yes
VSDAT [VSDAT]		08-Jun-2018
VSHGT [VSHGT]		172.0
VSWGT [VSWGT]		70.2
VSBMI [VSBMI]		23.7

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 09:00 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Height, Weight and BMI

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted] [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)	07-Aug-2018 02:04 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) algo pharm.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: [LBDAT]	08-Jun-2018
Time of Collection: [LBTIM]	11:23
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: Serology Lab Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	25-Jun-2018 09:04 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN [LBYN]		Yes
LBDAT [LBDAT]		08-Jun-2018
LBTIM [LBTIM]		11:23
LBNRIND [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 09:04 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".

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)	07-Aug-2018 02:04 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) algo pharm.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: [LBDAT]	
Time of Collection: [LBTIM]	
Time Unknown: [LBTMNK]	

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serum Pregnancy Test

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) algopharm.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? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	10:41
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	08-Jun-2018
Time Taken: [VSTIM]	10:46
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.5
Unit: [VSORRESU]	C

MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	122
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	77
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	61
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	19
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Screening
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 09:01 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]		10:41
VS1DAT [VSDAT]		08-Jun-2018
VSTIM [VSTIM]		10:46
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.5
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		122
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		77
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		61
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		19
[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 09:01 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:50 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
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:04 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) algopharm.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]	08-Jun-2018
Time of Collection: [LBTIM]	10:55
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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 09:02 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		08-Jun-2018
LBTIM3 [LBTIM]		10:55
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 09:02 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: UDS and Alcohol 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)	07-Aug-2018 02:04 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) algopharm.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]	08-Jun-2018
Time of Collection: [LBTIM]	10:55
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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 09:02 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN4 [LBYN]		Yes
LBDAT4 [LBDAT]		08-Jun-2018
LBTIM4 [LBTIM]		10:55
LBNRIND4 [LBNRIND]		No
[Row 1] LBTEST5 [LBTEST]		Cotinine
[Row 1] LBCLSIG4 [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 09:02 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Cotinine 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)	07-Aug-2018 02:04 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) algopharm.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]	08-Jun-2018
Time of Collection: [LBTIM]	11:23
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 09:05 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		08-Jun-2018
LBTIM5 [LBTIM]		11:23
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 09:05 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".
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)	07-Aug-2018 02:04 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) algopharm.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]	08-Jun-2018
Time of Collection: [LBTIM]	11:23
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 09:05 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		08-Jun-2018
LBTIM6 [LBTIM]		11:23
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 09:05 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".
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)	07-Aug-2018 02:04 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) algopharm.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]	08-Jun-2018
Time of Collection: [LBTIM]	10:55
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 09:04 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		08-Jun-2018
LBTIM7 [LBTIM]		10:55
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 09:04 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".
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)	07-Aug-2018 02:04 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) algopharm.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 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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]	08-Jun-2018
Visit: [EGVIS]	Screening

Row 1	
Time: [EGTIM]	10:39
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	59
PR Interval: [EGPR]	160
QRS Interval: [EGQRS]	96
QT Interval: [EGQT]	406
QTcB Interval: [EGQTCB]	403
QTcF: [EGQTCF]	404
Clinical Significance as per MD: [EGCLSIG]	NORMAL
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Screening
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 09:00 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT		08-Jun-2018

Variable	Old Value	New Value
[EGDAT]		
EGVIS [EGVIS]		Screening
[Row 1] EG1TIM [EGTIM]		10:39
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		59
[Row 1] EG1PR [EGPR]		160
[Row 1] EG1QRS [EGQRS]		96
[Row 1] EG1QT [EGQT]		406
[Row 1] EGQTCB [EGQTCB]		403
[Row 1] EG1QTCF [EGQTCF]		404
[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 09:00 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".

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)	07-Aug-2018 02:04 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 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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-1983

End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	
Daily Use: [SUDYUS]	20
Row 2	
Type of tobacco used? [SUTRT]	Cigar(s)
Frequency: [SUFRQ]	Never
Start Date: [SUSTDAT]	
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	
Daily Use: [SUDYUS]	
Row 3	
Type of tobacco used? [SUTRT]	Cigarillo(s)
Frequency: [SUFRQ]	Never
Start Date: [SUSTDAT]	

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

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

End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	
Daily Use: [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 11:20 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
[Row 1] SUTRT1 [SUTRT]		Cigarette(s)
[Row 1] SUFRQ1 [SUFRQ]		Current
[Row 1] SUSTDAT1 [SUSTDAT]		UN-UNK-1983
[Row 1] SUDYUS1 [SUDYUS]		20
[Row 2] SUTRT1 [SUTRT]		Cigar(s)
[Row 2] SUFRQ1 [SUFRQ]		Never
[Row 3] SUTRT1 [SUTRT]		Cigarillo(s)
[Row 3] SUFRQ1 [SUFRQ]		Never
[Row 4] SUTRT1 [SUTRT]		Chewing Tobacco
[Row 4] SUFRQ1		Never

Variable	Old Value	New Value
[SUFRQ]		
[Row 5] SUTRT1 [SUTRT]		Pipe(s)
[Row 5] SUFRQ1 [SUFRQ]		Never
[Row 6] SUTRT1 [SUTRT]		Nicotine Product(s): (patch, gum, etc)
[Row 6] SUFRQ1 [SUFRQ]		Never
[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 09:21 AM PDT (UTC-07:00)	Form marked as Complete
System	11-Jul-2018 11:20 AM PDT (UTC-07:00)	Form marked as Not Complete
System	11-Jul-2018 11:20 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:04 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 11:20 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 11:20 AM	16-Jul-2018 09:21 AM
	Description			
	New: Yearly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:20 AM (b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6) (b) (6)			
	[Row 1] SUWKUS1	NOT APPLICABLE [11-Jul-2018 11:21 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 11:20 AM	16-Jul-2018 09:21 AM
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:20 AM (b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6) (b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] SUMONUS1	NOT APPLICABLE [11-Jul-2018 11:21 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 11:20 AM	16-Jul-2018 09:21 AM
	Description			
	New: Monthly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:20 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? [SVYN]	Yes
Date of Visit: [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 09:46 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		22-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 09:46 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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) 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: Urine Pregnancy Test

Was Urine Pregnancy Test performed? [LBHCGYN]	
Date of collection: [LBDAT]	
Time of Collection: [LBTIM]	
Time Unknown: [LBTMNK]	

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Urine Pregnancy Test

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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	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 -1
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	07:12
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	22-Jun-2018
Time Taken: [VSTIM]	07:17
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.4
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure

Not done: [VSSTAT]	
Result: [VSORRES]	115
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	73
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	86
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	

Result: [VSORRES]	11
Unit: [VSORRESU]	breaths/min
MD Safety Review: [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 11:10 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]		07:12
VS1DAT [VSDAT]		22-Jun-2018
VSTIM [VSTIM]		07:17
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.4
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		115
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[VSCLSIG]		
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		73
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		86
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		11
[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 11:10 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:04 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) algopharm.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]	07:09
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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 11:08 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]		07:09
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 11:08 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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
(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)	07-Aug-2018 02:04 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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 11:11 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [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 11:11 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
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)	07-Aug-2018 02:04 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) 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? [SVYN]	Yes
Date of Visit: [SVSTDAT]	23-Jun-2018

AUDIT TRAIL

VISIT: Day 1
FORM: Visit Date

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	25-Jun-2018 11:14 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 11:14 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
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]	07-Aug-2018 02:04 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) 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 - 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 1
FORM: Part A - Usual Brand Dose Log

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:50 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) 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 - VLN Dosing Log

AD LIB VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG	
Date of Visit: [EXDAT]	23-Jun-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:40
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:42
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1

Time Dispensed: [EXTIM]	09:43
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:46
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:31
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:35
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:36
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:39
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:57

Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:01
Row 6	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:55
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:58
Row 7	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:59
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:01

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 09:07 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT1 [EXDAT]		23-Jun-2018
[Row 1] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD1 [EXDSPD]		1
[Row 1] EXTIM1 [EXTIM]		09:40
[Row 1] EXCIGRET1 [EXCIGRET]		1
[Row 1] EXTIMRET1 [EXTIMRET]		09:42
[Row 2] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD1 [EXDSPD]		1
[Row 2] EXTIM1 [EXTIM]		09:43
[Row 2] EXCIGRET1 [EXCIGRET]		1
[Row 2] EXTIMRET1 [EXTIMRET]		09:46
[Row 3] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD1 [EXDSPD]		1
[Row 3] EXTIM1 [EXTIM]		10:31
[Row 3] EXCIGRET1 [EXCIGRET]		1
[Row 3] EXTIMRET1 [EXTIMRET]		10:35
[Row 4] EXPRDT1		Combustible Cigarette

Variable	Old Value	New Value
[EXPRDT]		
[Row 4] EXDSPD1 [EXDSPD]		1
[Row 4] EXTIM1 [EXTIM]		10:36
[Row 4] EXCIGRET1 [EXCIGRET]		1
[Row 4] EXTIMRET1 [EXTIMRET]		10:39
[Row 5] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD1 [EXDSPD]		1
[Row 5] EXTIM1 [EXTIM]		11:57
[Row 5] EXCIGRET1 [EXCIGRET]		1
[Row 5] EXTIMRET1 [EXTIMRET]		12:01
[Row 6] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD1 [EXDSPD]		1
[Row 6] EXTIM1 [EXTIM]		12:55
[Row 6] EXCIGRET1 [EXCIGRET]		1
[Row 6] EXTIMRET1 [EXTIMRET]		12:58
[Row 7] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD1 [EXDSPD]		1
[Row 7] EXTIM1 [EXTIM]		12:59
[Row 7] EXCIGRET1 [EXCIGRET]		1
[Row 7] EXTIMRET1 [EXTIMRET]		13:01

FORM STATUS CHANGE LOG

VISIT: Day 1
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 09:07 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:51 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
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 08:52 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) 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 - 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 1
FORM: Part A - Nicorette Dosing Log

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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	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 1
FORM: Randomization

Date of Randomization: [DSRDAT]	23-Jun-2018
Randomization Number: [DSNUM]	1039
Sequence Group [DSRNGRP]	ABC

AUDIT TRAIL

VISIT: Day 1
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	25-Jun-2018 11:14 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]	22-Jun-2018	23-Jun-2018
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	25-Jun-2018 08:51 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		22-Jun-2018
DSRNUM [DSNUM]		1039
DSRNGRP [DSRNGRP]		ABC

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 11:14 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 11:14 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:51 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".
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)	07-Aug-2018 02:04 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Day 1
FORM: Randomization

ID	Variable	Responses/Reasons	Opened	Closed
	DSRNDAT	Data Updated [25-Jun-2018 11:14 AM]	25-Jun-2018 11:14 AM	25-Jun-2018 11:14 AM
	Description			
	New: Date differs from visit date **Old:** **By:** 25-Jun-2018 11:14 AM System			

ID	Variable	Responses/Reasons	Opened	Closed

LOCKING HISTORY

VISIT: Day 1
FORM: Randomization

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: 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 11:15 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

User	Date/Time	Change
System	25-Jun-2018 11:15 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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: [SVSTDAT]	24-Jun-2018

AUDIT TRAIL

VISIT: Day 2
FORM: Visit Date

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	25-Jun-2018 11:15 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [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 11:15 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
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]	07-Aug-2018 02:04 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]	24-Jun-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:40
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:44
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:04

Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:08
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:49
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:54
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:09
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:14
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:00
Number of Butts Returned: [EXCIGRET]	1

Time Returned: [EXTIMRET]	12:05
Row 6	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:49
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:55
Row 7	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:21
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:25
Row 8	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:26
Number of Butts Returned: [EXCIGRET]	1

Time Returned: [EXTIMRET]	13:30

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 09:17 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		24-Jun-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM [EXTIM]		09:40
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		09:44
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1
[Row 2] EXTIM [EXTIM]		10:04
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		10:08
[Row 3] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		10:49
[Row 3] EXCIGRET [EXCIGRET]		1

Variable	Old Value	New Value
[Row 3] EXTIMRET [EXTIMRET]		10:54
[Row 4] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		11:09
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		11:14
[Row 5] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD [EXDSPD]		1
[Row 5] EXTIM [EXTIM]		12:00
[Row 5] EXCIGRET [EXCIGRET]		1
[Row 5] EXTIMRET [EXTIMRET]		12:05
[Row 6] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD [EXDSPD]		1
[Row 6] EXTIM [EXTIM]		12:49
[Row 6] EXCIGRET [EXCIGRET]		1
[Row 6] EXTIMRET [EXTIMRET]		12:55
[Row 7] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD [EXDSPD]		1
[Row 7] EXTIM [EXTIM]		13:21
[Row 7] EXCIGRET [EXCIGRET]		1
[Row 7] EXTIMRET [EXTIMRET]		13:25

Variable	Old Value	New Value
[Row 8] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 8] EXDSPD [EXDSPD]		1
[Row 8] EXTIM [EXTIM]		13:26
[Row 8] EXCIGRET [EXCIGRET]		1
[Row 8] EXTIMRET [EXTIMRET]		13:30

FORM STATUS CHANGE LOG

VISIT: Day 2
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 09:17 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:51 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
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 08:53 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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]	
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 - VLN Dosing Log

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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 (b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

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 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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 11:15 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 11:15 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 08:28 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 08:28 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
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)	07-Aug-2018 02:04 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) 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 - 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 3
FORM: Part A - Usual Brand Dose Log

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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: [EXTIM]	
Number of Butts Returned: [EXCIGRET]	
Time Returned: [EXTIMRET]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) 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 - Nicorette Dosing Log

AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG	
Date of Visit: [EXDAT]	25-Jun-2018
Row 1	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:40
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	09:47

Row 2	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:53
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	11:09
Row 3	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:06
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	12:23
Row 4	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:57
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	13:19

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6)	
Date/Time	16-Aug-2018 01:55 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
[Row 1] EXTIMRET2 [EXTIMRET]	09:57	09:47
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 09:00 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT2 [EXDAT]		25-Jun-2018
[Row 1] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXDSPD2 [EXDSPD]		1
[Row 1] EXTIM2 [EXTIM]		09:40
[Row 1] EXNICRET [EXNICRET]		1
[Row 1] EXTIMRET2 [EXTIMRET]		09:57
[Row 2] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 2] EXDSPD2 [EXDSPD]		1
[Row 2] EXTIM2 [EXTIM]		10:53
[Row 2] EXNICRET [EXNICRET]		1
[Row 2] EXTIMRET2 [EXTIMRET]		11:09
[Row 3] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)

Variable	Old Value	New Value
[Row 3] EXDSPD2 [EXDSPD]		1
[Row 3] EXTIM2 [EXTIM]		12:06
[Row 3] EXNICRET [EXNICRET]		1
[Row 3] EXTIMRET2 [EXTIMRET]		12:23
[Row 4] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 4] EXDSPD2 [EXDSPD]		1
[Row 4] EXTIM2 [EXTIM]		12:57
[Row 4] EXNICRET [EXNICRET]		1
[Row 4] EXTIMRET2 [EXTIMRET]		13:19

FORM STATUS CHANGE LOG

VISIT: Day 3
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 09:00 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:51 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
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".

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)	19-Sep-2018 02:11 PM PDT (UTC-07:00)	Form marked as "Form Monitored".
(b) (6) vinceandassociates.com ((b) (6) (b) (6)	16-Aug-2018 01:55 PM PDT (UTC-07:00)	Data entry error (Form partially unmarked as "Form Monitored").(EXTIMRET2 [1])
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 08:54 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) algopharm.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? [QSPERF]	Yes
Use: [QSUSE]	1st Use

AUDIT TRAIL

VISIT: Day 3
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 08:29 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF		Yes

Variable	Old Value	New Value
[QSPERF]		
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 08:29 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
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)	07-Aug-2018 02:04 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 12:48 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 12:48 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".

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)	07-Aug-2018 02:04 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) 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: Randomization

Date of Randomization: [DSRDAT]	26-Jun-2018
Randomization Number: [DSNUM]	2038
Sequence Group [DSRNGRP]	ABC

AUDIT TRAIL

VISIT: Day 4
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 12:33 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		26-Jun-2018

Variable	Old Value	New Value
DSRNUM [DSNUM]		2038
DSRNGRP [DSRNGRP]		ABC

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 12:33 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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) 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 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 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) 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 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 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) 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 - 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 4
FORM: Part B - Uncontrolled Usual Brand Dosing Log

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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]	
Session Start Time: [EXSTTIM]	
Row 1	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	

Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	
If yes, provide reason: [EXCOM]	

Did the subject consume any beverages during controlled product use? [EXBEVB]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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) 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 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]	26-Jun-2018

Session Start Time: [EXSTTIM]	09:40
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:40:00
Puff End: [EXPFEN]	09:40:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	09:40:30
Puff End: [EXPFEN]	09:40:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:41:00
Puff End: [EXPFEN]	09:41:03
Missed Puff: [EXMISPF]	No

If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:41:30
Puff End: [EXPFEN]	09:41:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:42:00
Puff End: [EXPFEN]	09:42:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:42:30
Puff End: [EXPFEN]	09:42:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:43:00
Puff End: [EXPFEN]	09:43:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:43:30
Puff End: [EXPFEN]	09:43:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	Yes
If yes, provide reason: [EXCOM]	FINISHED CIGARETTE

Row 10	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	Yes
If yes, provide reason: [EXCOM]	FINISHED CIGARETTE

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 01:11 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATVLN [EXDATVLN]		26-Jun-2018
EXSTTIM [EXSTTIM]		09:40
[Row 1] EXPFF [EXPFF]		Puff 1
[Row 1] EXPFBG [EXPFBG]		09:40:00
[Row 1] EXPFEN [EXPFEN]		09:40:04
[Row 1] EXMISPF [EXMISPF]		No
[Row 2] EXPFF [EXPFF]		Puff 2
[Row 2] EXPFBG		09:40:30

Variable	Old Value	New Value
[EXPFBG]		
[Row 2] EXPFEN [EXPFEN]		09:40:33
[Row 2] EXMISPF [EXMISPF]		No
[Row 3] EXPFF [EXPFF]		Puff 3
[Row 3] EXPFBG [EXPFBG]		09:41:00
[Row 3] EXPFEN [EXPFEN]		09:41:03
[Row 3] EXMISPF [EXMISPF]		No
[Row 4] EXPFF [EXPFF]		Puff 4
[Row 4] EXPFBG [EXPFBG]		09:41:30
[Row 4] EXPFEN [EXPFEN]		09:41:33
[Row 4] EXMISPF [EXMISPF]		No
[Row 5] EXPFF [EXPFF]		Puff 5
[Row 5] EXPFBG [EXPFBG]		09:42:00
[Row 5] EXPFEN [EXPFEN]		09:42:03
[Row 5] EXMISPF [EXMISPF]		No
[Row 6] EXPFF [EXPFF]		Puff 6
[Row 6] EXPFBG [EXPFBG]		09:42:30
[Row 6] EXPFEN [EXPFEN]		09:42:33
[Row 6] EXMISPF [EXMISPF]		No
[Row 7] EXPFF [EXPFF]		Puff 7
[Row 7] EXPFBG [EXPFBG]		09:43:00
[Row 7] EXPFEN [EXPFEN]		09:43:03

Variable	Old Value	New Value
[Row 7] EXMISPF [EXMISPF]		No
[Row 8] EXPFF [EXPFF]		Puff 8
[Row 8] EXPFBG [EXPFBG]		09:43:30
[Row 8] EXPFEN [EXPFEN]		09:43:33
[Row 8] EXMISPF [EXMISPF]		No
[Row 9] EXMISPF [EXMISPF]		Yes
[Row 9] EXCOM [EXCOM]		FINISHED CIGARETTE
[Row 10] EXMISPF [EXMISPF]		Yes
[Row 10] EXCOM [EXCOM]		FINISHED CIGARETTE
EXBEVB2 [EXBEVB2]		No

FORM STATUS CHANGE LOG

VISIT: Day 4
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	27-Jun-2018 01:11 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:33 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
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 08:55 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) 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 - 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]	26-Jun-2018
Session Start Time: [EXSRTTIM]	15:40
Session End Time: [EXENDTIM]	15:42

Row 1	
Inhalation Begin: [EXINHBG]	15:40:02
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:03
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:40:06
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:07
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:40:17
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:18
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:40:30
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:32

Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:40:57
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:59
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:41:15
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:41:18
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:41:42
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:41:45
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:42:02
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	15:42:05
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:42:21
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:42:23
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:42:32
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:42:35
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	15:42:36
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:42:37
Time Unknown: [EXTIMUNK]	

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

Session Total Inhalations: [EXINTOT]	11

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 01:15 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX9DATB [EXDATB]		26-Jun-2018
EX9SRTTIM [EXSRTTIM]		15:40
EX9ENDTIM [EXENDTIM]		15:42
[Row 1] EX9INHBG [EXINHBG]		15:40:02
[Row 1] EX9INEN [EXINEN]		15:40:03
[Row 2] EX9INHBG [EXINHBG]		15:40:06
[Row 2] EX9INEN [EXINEN]		15:40:07
[Row 3] EX9INHBG [EXINHBG]		15:40:17
[Row 3] EX9INEN [EXINEN]		15:40:18
[Row 4] EX9INHBG [EXINHBG]		15:40:30
[Row 4] EX9INEN [EXINEN]		15:40:32
[Row 5] EX9INHBG [EXINHBG]		15:40:57
[Row 5] EX9INEN [EXINEN]		15:40:59
[Row 6] EX9INHBG [EXINHBG]		15:41:15
[Row 6] EX9INEN [EXINEN]		15:41:18
[Row 7] EX9INHBG		15:41:42

Variable	Old Value	New Value
[EXINHBG]		
[Row 7] EX9INEN [EXINEN]		15:41:45
[Row 8] EX9INHBG [EXINHBG]		15:42:02
[Row 8] EX9INEN [EXINEN]		15:42:05
[Row 9] EX9INHBG [EXINHBG]		15:42:21
[Row 9] EX9INEN [EXINEN]		15:42:23
[Row 10] EX9INHBG [EXINHBG]		15:42:32
[Row 10] EX9INEN [EXINEN]		15:42:35
[Row 11] EX9INHBG [EXINHBG]		15:42:36
[Row 11] EX9INEN [EXINEN]		15:42:37
EX9BEVB [EXBEVB]		No
EX9INTOT [EXINTOT]		11

FORM STATUS CHANGE LOG

VISIT: Day 4
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
System	27-Jun-2018 01:15 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:33 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
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 08:56 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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 08:47 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 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 08:47 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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: [QSPERF]	Yes
Use: [QSUSE]	2nd Use
Row 1	
Time point: [QSTMPT]	
Completed: [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 08:47 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 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 08:47 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	28-Jun-2018 08:47 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 08:47 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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
(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)	07-Aug-2018 02:04 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) 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 - 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	28-Jun-2018 08:47 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 08:47 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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**
[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]	07-Aug-2018 02:04 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: [PKTPT]	Predose
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:42

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:46
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:47
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:25

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	11:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	11:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	12:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	12:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [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 08:44 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]		26-Jun-2018
[Row 1] PKTIM [PKTIM]		09:35
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		26-Jun-2018
[Row 2] PKTIM [PKTIM]		09:42
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		26-Jun-2018
[Row 3] PKTIM [PKTIM]		09:46
[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]		09:47
[Row 5] PKTPT [PKTPT]		10 minute

Variable	Old Value	New Value
[Row 5] PKDAT [PKDAT]		26-Jun-2018
[Row 5] PKTIM [PKTIM]		09:50
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		26-Jun-2018
[Row 6] PKTIM [PKTIM]		09:52
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		26-Jun-2018
[Row 7] PKTIM [PKTIM]		09:55
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		26-Jun-2018
[Row 8] PKTIM [PKTIM]		10:00
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		26-Jun-2018
[Row 9] PKTIM [PKTIM]		10:10
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		26-Jun-2018
[Row 10] PKTIM [PKTIM]		10:25
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		26-Jun-2018
[Row 11] PKTIM [PKTIM]		10:41
[Row 11] PKCODE [PKCODE]		B - Late due to previous procedure

Variable	Old Value	New Value
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		26-Jun-2018
[Row 12] PKTIM [PKTIM]		11:11
[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]		11:40
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		26-Jun-2018
[Row 14] PKTIM [PKTIM]		12:10
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		26-Jun-2018
[Row 15] PKTIM [PKTIM]		12:40

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 08:44 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:35

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:42
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:46
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:47
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:56
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:11

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	17:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	18:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	18:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [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 08:46 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		26-Jun-2018
[Row 1] PKTIM1 [PKTIM]		15:35
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		26-Jun-2018
[Row 2] PKTIM1		15:42

Variable	Old Value	New Value
[PKTIM]		
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		26-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:46
[Row 3] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		26-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:47
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		26-Jun-2018
[Row 5] PKTIM1 [PKTIM]		15:50
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		26-Jun-2018
[Row 6] PKTIM1 [PKTIM]		15:52
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		26-Jun-2018
[Row 7] PKTIM1 [PKTIM]		15:56
[Row 7] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		26-Jun-2018
[Row 8] PKTIM1 [PKTIM]		16:00
[Row 9] PKTPT1 [PKTPT]		30 minute

Variable	Old Value	New Value
[Row 9] PKDAT1 [PKDAT]		26-Jun-2018
[Row 9] PKTIM1 [PKTIM]		16:11
[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]		16:25
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		26-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:41
[Row 11] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		26-Jun-2018
[Row 12] PKTIM1 [PKTIM]		17:11
[Row 12] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		26-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:40
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		26-Jun-2018
[Row 14] PKTIM1 [PKTIM]		18:10
[Row 15] PKTPT1 [PKTPT]		180 minute

Variable	Old Value	New Value
[Row 15] PKDAT1 [PKDAT]		26-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:40

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 08:46 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 08:47 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 08:47 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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**
(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)	07-Aug-2018 02:04 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) 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: 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 08:47 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 08:47 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 08:49 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 08:49 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 5
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)	07-Aug-2018 02:04 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) 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 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]	
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 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 Not Expected

User	Date/Time	Change
System	16-May-2018 03:05 PM PDT (UTC-07:00)	Form marked as Not Complete

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]	

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 5
FORM: Part B - Uncontrolled Nicorette Dosing Log

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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) 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 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]	27-Jun-2018
Session Start Time: [EXSRTTIM]	15:40
Session End Time: [EXENDTIM]	15:44
Row 1	
Inhalation Begin: [EXINHBG]	15:40:00
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:03
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:40:15

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:18
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:40:53
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:40:54
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:41:11
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:41:12
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:41:49
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:41:52
Time Unknown: [EXTIMUNK]	

Row 6	
Inhalation Begin: [EXINHBG]	15:42:13
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:42:16
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:42:34
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:42:36
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:42:54
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:42:55
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:43:18
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:43:20

Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:43:58
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:44:02
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	15:44:17
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:44:18
Time Unknown: [EXTIMUNK]	
Row 12	
Inhalation Begin: [EXINHBG]	15:44:24
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:44:26
Time Unknown: [EXTIMUNK]	
Row 13	
Inhalation Begin: [EXINHBG]	15:44:28
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	15:44:29
Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	13

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	30-Aug-2018 08:42 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
[Row 3] EXINHBG [EXINHBG]	14:50:53	15:40:53
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 01:52 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATB [EXDATB]		27-Jun-2018
EXSRTTIM [EXSRTTIM]		15:40
EXENDTIM [EXENDTIM]		15:44
[Row 1] EXINHBG [EXINHBG]		15:40:00
[Row 1] EXINEN [EXINEN]		15:40:03
[Row 2] EXINHBG [EXINHBG]		15:40:15

Variable	Old Value	New Value
[Row 2] EXINEN [EXINEN]		15:40:18
[Row 3] EXINHBG [EXINHBG]		14:50:53
[Row 3] EXINEN [EXINEN]		15:40:54
[Row 4] EXINHBG [EXINHBG]		15:41:11
[Row 4] EXINEN [EXINEN]		15:41:12
[Row 5] EXINHBG [EXINHBG]		15:41:49
[Row 5] EXINEN [EXINEN]		15:41:52
[Row 6] EXINHBG [EXINHBG]		15:42:13
[Row 6] EXINEN [EXINEN]		15:42:16
[Row 7] EXINHBG [EXINHBG]		15:42:34
[Row 7] EXINEN [EXINEN]		15:42:36
[Row 8] EXINHBG [EXINHBG]		15:42:54
[Row 8] EXINEN [EXINEN]		15:42:55
[Row 9] EXINHBG [EXINHBG]		15:43:18
[Row 9] EXINEN [EXINEN]		15:43:20
[Row 10] EXINHBG [EXINHBG]		15:43:58
[Row 10] EXINEN [EXINEN]		15:44:02
[Row 11] EXINHBG [EXINHBG]		15:44:17
[Row 11] EXINEN [EXINEN]		15:44:18
[Row 12] EXINHBG [EXINHBG]		15:44:24
[Row 12] EXINEN [EXINEN]		15:44:26

Variable	Old Value	New Value
[Row 13] EXINHBG [EXINHBG]		15:44:28
[Row 13] EXINEN [EXINEN]		15:44:29
EXBEVB [EXBEVB]		No
EXINTOT [EXINTOT]		13

FORM STATUS CHANGE LOG

VISIT: Day 5
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	11-Sep-2018 11:20 AM PDT (UTC-07:00)	Form marked as Complete
System	28-Aug-2018 08:44 AM PDT (UTC-07:00)	Form marked as Not Complete
System	28-Jun-2018 01:52 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:33 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 5
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)	19-Sep-2018 02:12 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

User	Date/Time	Status
(b) (6) vinceandassociates.com (b) (6)	30-Aug-2018 08:42 AM PDT (UTC-07:00)	Data entry error (Form partially unmarked as "Form Monitored").(EXINHBG [3])
(b) (6) gmail.com (b) (b) (b) (6)	02-Aug-2018 08:58 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

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

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 3] EXINHBG	DATA HAS BEEN UPDATED [30-Aug-2018 08:44 AM by (b) (6) vinceandassociates.com (b) (6) Response satisfies query [11-Sep-2018 11:20 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	28-Aug-2018 08:44 AM	11-Sep-2018 11:20 AM
	Description			
	New: Please verify and confirm if the time entered is correct. Thanks **Old:** **By:** 28-Aug-2018 08:44 AM (b) (6) algopharm.com (b) (6) (b) (6)			

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) 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 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]	27-Jun-2018
Session Start Time: [EXSTTIM]	09:40
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:40:02
Puff End: [EXPFEN]	09:40:05
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	09:40:30
Puff End: [EXPFEN]	09:40:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:41:00
Puff End: [EXPFEN]	09:41:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:41:30
Puff End: [EXPFEN]	09:41:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:42:00
Puff End: [EXPFEN]	09:42:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:42:30
Puff End: [EXPFEN]	09:42:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:43:00
Puff End: [EXPFEN]	09:43:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:43:30
Puff End: [EXPFEN]	09:43:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:44:01
Puff End: [EXPFEN]	09:44:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 10	
Puff: [EXPFF]	Puff 10
Puff Begin: [EXPFBG]	09:44:30
Puff End: [EXPFEN]	09:44:34
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Did the subject consume any beverages during controlled product use? [EXBEVB]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 01:49 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX8DATVLN		27-Jun-2018

Variable	Old Value	New Value
[EXDATVLN]		
EX8STTIM [EXSTTIM]		09:40
[Row 1] EX8PFF [EXPFF]		Puff 1
[Row 1] EX8PFBG [EXPFBG]		09:40:02
[Row 1] EX8PFEN [EXPFEN]		09:40:05
[Row 1] EX8MISPF [EXMISPF]		No
[Row 2] EX8PFF [EXPFF]		Puff 2
[Row 2] EX8PFBG [EXPFBG]		09:40:30
[Row 2] EX8PFEN [EXPFEN]		09:40:33
[Row 2] EX8MISPF [EXMISPF]		No
[Row 3] EX8PFF [EXPFF]		Puff 3
[Row 3] EX8PFBG [EXPFBG]		09:41:00
[Row 3] EX8PFEN [EXPFEN]		09:41:03
[Row 3] EX8MISPF [EXMISPF]		No
[Row 4] EX8PFF [EXPFF]		Puff 4
[Row 4] EX8PFBG [EXPFBG]		09:41:30
[Row 4] EX8PFEN [EXPFEN]		09:41:33
[Row 4] EX8MISPF [EXMISPF]		No
[Row 5] EX8PFF [EXPFF]		Puff 5
[Row 5] EX8PFBG [EXPFBG]		09:42:00
[Row 5] EX8PFEN [EXPFEN]		09:42:03
[Row 5] EX8MISPF [EXMISPF]		No

Variable	Old Value	New Value
[Row 6] EX8PFF [EXPFF]		Puff 6
[Row 6] EX8PFBG [EXPFBG]		09:42:30
[Row 6] EX8PFEN [EXPFEN]		09:42:33
[Row 6] EX8MISPF [EXMISPF]		No
[Row 7] EX8PFF [EXPFF]		Puff 7
[Row 7] EX8PFBG [EXPFBG]		09:43:00
[Row 7] EX8PFEN [EXPFEN]		09:43:03
[Row 7] EX8MISPF [EXMISPF]		No
[Row 8] EX8PFF [EXPFF]		Puff 8
[Row 8] EX8PFBG [EXPFBG]		09:43:30
[Row 8] EX8PFEN [EXPFEN]		09:43:33
[Row 8] EX8MISPF [EXMISPF]		No
[Row 9] EX8PFF [EXPFF]		Puff 9
[Row 9] EX8PFBG [EXPFBG]		09:44:01
[Row 9] EX8PFEN [EXPFEN]		09:44:04
[Row 9] EX8MISPF [EXMISPF]		No
[Row 10] EX8PFF [EXPFF]		Puff 10
[Row 10] EX8PFBG [EXPFBG]		09:44:30
[Row 10] EX8PFEN [EXPFEN]		09:44:34
[Row 10] EX8MISPF [EXMISPF]		No
EX8BEVB [EXBEVB]		No

FORM STATUS CHANGE LOG

VISIT: Day 5
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	28-Jun-2018 01:49 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:33 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 5
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 08:57 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) 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 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: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	
If yes, provide reason: [EXCOM]	

Did the subject consume any beverages during controlled product use? [EXBEVB2]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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: [EXINTOT]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) 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: 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 5
FORM: 1st Use - Tobacco/Nicotine Questionnaire

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	28-Jun-2018 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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]	07-Aug-2018 02:04 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 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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: [QSUSE]	1st Use

Row 1	
Time point: [QSTMPT]	
Completed: [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 08:54 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 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 08:54 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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]	07-Aug-2018 02:04 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: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:42

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:46
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:47
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:56
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:25

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	11:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	11:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	12:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	12:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [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 08:51 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]		27-Jun-2018
[Row 1] PKTIM [PKTIM]		09:35
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		27-Jun-2018
[Row 2] PKTIM [PKTIM]		09:42
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		27-Jun-2018
[Row 3] PKTIM [PKTIM]		09:46
[Row 3] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		27-Jun-2018
[Row 4] PKTIM [PKTIM]		09:47
[Row 5] PKTPT [PKTPT]		10 minute

Variable	Old Value	New Value
[Row 5] PKDAT [PKDAT]		27-Jun-2018
[Row 5] PKTIM [PKTIM]		09:50
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		27-Jun-2018
[Row 6] PKTIM [PKTIM]		09:52
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		27-Jun-2018
[Row 7] PKTIM [PKTIM]		09:56
[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]		10:00
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		27-Jun-2018
[Row 9] PKTIM [PKTIM]		10:11
[Row 9] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		27-Jun-2018
[Row 10] PKTIM [PKTIM]		10:25
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		27-Jun-2018

Variable	Old Value	New Value
[Row 11] PKTIM [PKTIM]		10:40
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		27-Jun-2018
[Row 12] PKTIM [PKTIM]		11:11
[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]		11:40
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		27-Jun-2018
[Row 14] PKTIM [PKTIM]		12:10
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		27-Jun-2018
[Row 15] PKTIM [PKTIM]		12:40

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 08:51 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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]	15:35

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:42
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:46
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:47
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:56
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:10

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	18:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	18:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [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 08:53 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		27-Jun-2018
[Row 1] PKTIM1 [PKTIM]		15:35
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		27-Jun-2018
[Row 2] PKTIM1		15:42

Variable	Old Value	New Value
[PKTIM]		
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		27-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:46
[Row 3] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		27-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:47
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		27-Jun-2018
[Row 5] PKTIM1 [PKTIM]		15:50
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		27-Jun-2018
[Row 6] PKTIM1 [PKTIM]		15:52
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		27-Jun-2018
[Row 7] PKTIM1 [PKTIM]		15:56
[Row 7] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		27-Jun-2018
[Row 8] PKTIM1 [PKTIM]		16:00
[Row 9] PKTPT1 [PKTPT]		30 minute

Variable	Old Value	New Value
[Row 9] PKDAT1 [PKDAT]		27-Jun-2018
[Row 9] PKTIM1 [PKTIM]		16:10
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		27-Jun-2018
[Row 10] PKTIM1 [PKTIM]		16:25
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		27-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:41
[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]		17:10
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		27-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:40
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		27-Jun-2018
[Row 14] PKTIM1 [PKTIM]		18:10
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		27-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:40

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 08:53 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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: [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 08:54 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 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 08:54 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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) 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 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 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:04 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 08:56 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 08:56 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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]	07-Aug-2018 02:11 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]	Yes
Time Seated: [VS1TIMS]	18:50
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	28-Jun-2018
Time Taken: [VSTIM]	18:55
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.9
Unit: [VSORRESU]	C

MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	111
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	72
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	67
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	14
Unit: [VSORRESU]	breaths/min
MD Safety Review: [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 12:01 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		Yes
VSTIMS [VS1TIMS]		18:50
VS1DAT [VSDAT]		28-Jun-2018
VSTIM [VSTIM]		18:55
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.9
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		111
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		72
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		67
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		14
[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 12:01 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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]	18:40
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: Chemistry Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 10:03 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]		18:40
LBNRIND5 [LBNRIND]		Yes

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 10:03 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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]	18:40
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 10:03 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]		18:40
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 10:03 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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]	06:30
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: Urinalysis Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 10:03 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		28-Jun-2018
LBTIM7 [LBTIM]		06:30
LBNRIND7 [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 10:03 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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: [PETEST]	
Not done: [PESTAT]	
Examination Results: [PEORRES]	
Abnormal Findings: [PECLSIG]	
If Other, please specify: [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 12:01 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [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 12:01 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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]	28-Jun-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	09:40

Session End Time: [EXENTMB]	09:50

Did the subject consume any beverages during controlled product use?: [EXBEV]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 01:53 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT [EXNICDAT]		28-Jun-2018
[Row 1] EXPRDB [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB [EXSRTTIMB]		09:40
[Row 1] EXENTMB [EXENTMB]		09:50
EXBEV [EXBEV]		No

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 01:53 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:33 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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 08:59 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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: [EXNICDAT]	28-Jun-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	15:40

Session End Time: [EXENTMB]	15:50

Did the subject consume any beverages during controlled product use?: [EXBEV]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 09:31 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT2 [EXNICDAT]		28-Jun-2018
[Row 1] EXPRDB2 [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB2 [EXSRTTIMB]		15:40
[Row 1] EXENTMB2 [EXENTMB]		15:50
EXBEV2 [EXBEV]		No

FORM STATUS CHANGE LOG

VISIT: Day 6
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	29-Jun-2018 09:31 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:33 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
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
(b) (6) gmail.com (b) (6) (b) (6)	02-Aug-2018 08:59 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) 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 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: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	
If yes, provide reason: [EXCOM]	

Did the subject consume any beverages during controlled product use? [EXBEVB]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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: [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 6
FORM: Part B - Uncontrolled Usual Brand Dosing Log

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:50 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]	
Session Start Time: [EXSTTIM]	
Row 1	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	
If yes, provide reason: [EXCOM]	

Did the subject consume any beverages during controlled product use? [EXBEVB2]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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) 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 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: [EXINTOT]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

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) 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: ECG Test Results

Was the ECG performed? [EGYN]	Yes
Date: [EGDAT]	28-Jun-2018
Visit: [EGVIS]	Day 6
Row 1	
Time: [EGTIM]	18:48
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	64
PR Interval: [EGPR]	163
QRS Interval: [EGQRS]	100
QT Interval: [EGQT]	390
QTcB Interval: [EGQTCB]	403
QTcF: [EGQTCF]	398
Clinical Significance as per MD: [EGCLSIG]	NORMAL
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Day 6
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 12:00 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]		18:48
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		64
[Row 1] EG1PR [EGPR]		163
[Row 1] EG1QRS [EGQRS]		100
[Row 1] EG1QT [EGQT]		390
[Row 1] EGQTCB [EGQTCB]		403
[Row 1] EG1QTCF [EGQTCF]		398
[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 12:00 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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: [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 12:06 PM 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 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 12:06 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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 12:06 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 12:06 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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: [QSPERF]	Yes
Use: [QSUSE]	1st Use

Row 1	
Time point: [QSTMPT]	
Completed: [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 12:06 PM 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 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 12:06 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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 12:06 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 12:06 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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]	07-Aug-2018 02:11 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 12:01 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 12:01 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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]	09:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:42

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:47
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:25

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	11:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	11:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	12:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	12:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [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 11:58 AM 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 [PKTIM]		10:11
[Row 9] PKACTNK [PKACTNK]	No	
[Row 9] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 10] PKTIM [PKTIM]		10:25
[Row 10] PKACTNK [PKACTNK]	No	
[Row 11] PKTIM [PKTIM]		10:41
[Row 11] PKACTNK [PKACTNK]	No	
[Row 11] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 12] PKTIM [PKTIM]		11:11
[Row 12] PKACTNK [PKACTNK]	No	
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTIM [PKTIM]		11:40
[Row 13] PKACTNK [PKACTNK]	No	
[Row 14] PKTIM [PKTIM]		12:10

Variable	Old Value	New Value
[Row 14] PKACTNK [PKACTNK]	No	
[Row 15] PKTIM [PKTIM]		12:40
[Row 15] PKACTNK [PKACTNK]	No	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 08:58 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]		09:35
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		28-Jun-2018
[Row 2] PKTIM [PKTIM]		09:42
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		28-Jun-2018
[Row 3] PKTIM [PKTIM]		09:45
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		28-Jun-2018
[Row 4] PKTIM [PKTIM]		09:47
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		28-Jun-2018
[Row 5] PKTIM		09:50

Variable	Old Value	New Value
[PKTIM]		
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		28-Jun-2018
[Row 6] PKTIM [PKTIM]		09:52
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		28-Jun-2018
[Row 7] PKTIM [PKTIM]		09:55
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		28-Jun-2018
[Row 8] PKTIM [PKTIM]		10:00
[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

Variable	Old Value	New Value
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		28-Jun-2018
[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 11:58 AM PDT (UTC-07:00)	Form marked as Complete
System	28-Jun-2018 08:58 AM PDT (UTC-07:00)	Form marked as Not Complete
System	28-Jun-2018 08:58 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".

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)	07-Aug-2018 02:11 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 11:58 AM by (b) (6) vinceandassociates.com ((b) (6)	28-Jun-2018 08:58 AM	29-Jun-2018 11:58 AM
	Description			
	New: Time is missing, please review. **Old:** **By:** 28-Jun-2018 08:58 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 14] PKTIM	Data Updated [29-Jun-2018 11:58 AM by (b) (6) vinceandassociates.com ((b) (6)	28-Jun-2018 08:58 AM	29-Jun-2018 11:58 AM
	Description			
	New: Time is missing, please review. **Old:** **By:** 28-Jun-2018 08:58 AM (b) (6) vinceandassociates.com ((b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 13] PKTIM	Data Updated [29-Jun-2018 11:58 AM by (b) (6) vinceandassociates.com ((b) (6)	28-Jun-2018 08:58 AM	29-Jun-2018 11:58 AM
	Description			
	New: Time is missing, please review. **Old:** **By:** 28-Jun-2018 08:58 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 12] PKTIM	Data Updated [29-Jun-2018 11:58 AM by (b) (6) vinceandassociates.com ((b) (6)	28-Jun-2018 08:58 AM	29-Jun-2018 11:58 AM
	Description			
	New: Time is missing, please review. **Old:** **By:** 28-Jun-2018 08:58 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 11] PKTIM	Data Updated [29-Jun-2018 11:58 AM by (b) (6) vinceandassociates.com ((b) (6)	28-Jun-2018 08:58 AM	29-Jun-2018 11:58 AM
	Description			
	New: Time is missing, please review. **Old:** **By:** 28-Jun-2018 08:58 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 10] PKTIM	Data Updated [29-Jun-2018 11:58 AM by (b) (6) vinceandassociates.com ((b) (6)	28-Jun-2018 08:58 AM	29-Jun-2018 11:58 AM
	Description			
	New: Time is missing, please review. **Old:**			

ID	Variable	Responses/Reasons	Opened	Closed
	By: 28-Jun-2018 08:58 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 9] PKTIM	Data Updated [29-Jun-2018 11:58 AM by (b) (6) vinceandassociates.com ((b) (6)	28-Jun-2018 08:58 AM	29-Jun-2018 11:58 AM
	Description			
	New: Time is missing, please review. **Old:** **By:** 28-Jun-2018 08:58 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) 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 - PK Blood Sampling

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:35
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:42
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	28-Jun-2018

Time: [PKTIM]	15:47
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:10
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	28-Jun-2018

Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	18:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	18:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [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 11:59 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		28-Jun-2018
[Row 1] PKTIM1 [PKTIM]		15:35
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		28-Jun-2018
[Row 2] PKTIM1 [PKTIM]		15:42
[Row 3] PKTPT1 [PKTPT]		5 minute

Variable	Old Value	New Value
[Row 3] PKDAT1 [PKDAT]		28-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:45
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		28-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:47
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		28-Jun-2018
[Row 5] PKTIM1 [PKTIM]		15:50
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		28-Jun-2018
[Row 6] PKTIM1 [PKTIM]		15:52
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		28-Jun-2018
[Row 7] PKTIM1 [PKTIM]		15:55
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		28-Jun-2018
[Row 8] PKTIM1 [PKTIM]		16:00
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		28-Jun-2018
[Row 9] PKTIM1 [PKTIM]		16:10
[Row 10] PKTPT1 [PKTPT]		45 minute

Variable	Old Value	New Value
[Row 10] PKDAT1 [PKDAT]		28-Jun-2018
[Row 10] PKTIM1 [PKTIM]		16:25
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		28-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:40
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		28-Jun-2018
[Row 12] PKTIM1 [PKTIM]		17:10
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		28-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:40
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		28-Jun-2018
[Row 14] PKTIM1 [PKTIM]		18:10
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		28-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:40

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

User	Date/Time	Change
System	29-Jun-2018 11:59 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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".
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)	07-Aug-2018 02:11 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) 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 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	29-Jun-2018 12:07 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 12:07 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 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**
[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]	07-Aug-2018 02:11 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: [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 12:07 PM 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 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 12:07 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:50 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)	07-Aug-2018 02:11 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 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) 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: Vital Signs

Visit: [VSVIS]	
Were vital signs measured? [VSPERF]	
Repeat vital signs? [VSPERFR]	
Time Seated: [VS1TIMS]	
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	
Time Taken: [VSTIM]	
Time Unknown: [VSTMNK]	

Row 1	
Assessment: [VSTEST]	
Not done: [VSSTAT]	
Result: [VSORRES]	
Unit: [VSORRESU]	
MD Safety Review: [VSCLSIG]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Vital Signs

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) algopharm.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 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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: [LBTEST]	
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [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 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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) algopharm.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: [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: Urinalysis Laboratory Evaluation

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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: [PEVIS]	
Was physical examination performed? [PEYN]	
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]	

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 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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? [EGYN]	
Date: [EGDAT]	
Visit: [EGVIS]	

Row 1	
Time: [EGTIM]	
Time Unknown: [EGTMNK]	
Position: [EGPOS]	
VR: [EGVR]	
PR Interval: [EGPR]	
QRS Interval: [EGQRS]	
QT Interval: [EGQT]	
QTcB Interval: [EGQTCB]	
QTcF: [EGQTCF]	
Clinical Significance as per MD: [EGCLSIG]	
If Abnormal and Clinically Significant, please specify abnormalities: [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 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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: [DSCOM]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: End of Study

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:50 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 (b) (6) (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: [PKUSE]	

Row 1	
Timepoint: [PKTPT]	
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [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 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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: [PKUSE]	
Row 1	
Timepoint: [PKTPT]	
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [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 12:25 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:50 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? [AEYN]	Yes
Row 1	
AE Identifier: [AESPID]	1
Adverse Event Term: [AETERM]	CHEST DISCOMFORT
Is this an SAE? [AESER]	No
Severity: [AESEV]	MILD

Frequency: [AEFREQ]	Continuous
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	No
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Probably Related
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	25-Jun-2018
Onset Time: [AESTTIM]	10:55
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	25-Jun-2018
End Time: [AEENTIM]	11:08
Time Unknown: [AEENTMNK]	
Row 2	
AE Identifier: [AESPID]	2
Adverse Event Term: [AETERM]	HICCUPS

Is this an SAE? [AESER]	No
Severity: [AESEV]	MILD
Frequency: [AEFREQ]	Single Episode
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	No
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Probably Related
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	25-Jun-2018
Onset Time: [AESTTIM]	10:55
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	25-Jun-2018
End Time: [AEENTIM]	10:59
Time Unknown: [AEENTMNK]	

Row 3	
AE Identifier: [AESPID]	3
Adverse Event Term: [AETERM]	HICCUPS
Is this an SAE? [AESER]	No
Severity: [AESEV]	MILD
Frequency: [AEFREQ]	Intermittent
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	No
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Probably Related
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	25-Jun-2018
Onset Time: [AESTTIM]	12:06
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	25-Jun-2018

End Time: [AEENTIM]	13:15
Time Unknown: [AEENTMNK]	

AUDIT TRAIL

VISIT: All Visits
FORM: Adverse Events

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 12:26 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 3] AEDIS [AEDIS]		No
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 02:04 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 2] AESPID [AESPID]		2
[Row 2] AETERM [AETERM]		HICCUPS
[Row 2] AESER [AESER]		No
[Row 2] AESEV [AESEV]		MILD
[Row 2] AEFREQ [AEFREQ]		Single Episode
[Row 2] AEACN [AEACN]		No Action Taken
[Row 2] AECONTRT [AECONTRT]		No
[Row 2] AEDIS [AEDIS]		No
[Row 2] AEREL		Probably Related

Variable	Old Value	New Value
[AEREL]		
[Row 2] AETEAE [AETEAE]		No
[Row 2] AEOUT [AEOUT]		Resolved
[Row 2] AESTDAT [AESTDAT]		25-Jun-2018
[Row 2] AESTTIM [AESTTIM]		10:55
[Row 2] AEONGO [AEONGO]		No
[Row 2] AEENDAT [AEENDAT]		25-Jun-2018
[Row 2] AEENTIM [AEENTIM]		10:59
[Row 3] AESPID [AESPID]		3
[Row 3] AETERM [AETERM]		HICCUPS
[Row 3] AESER [AESER]		No
[Row 3] AESEV [AESEV]		MILD
[Row 3] AEFREQ [AEFREQ]		Intermittent
[Row 3] AEACN [AEACN]		No Action Taken
[Row 3] AECONTRT [AECONTRT]		No
[Row 3] AEREL [AEREL]		Probably Related
[Row 3] AETEAE [AETEAE]		No
[Row 3] AEOUT [AEOUT]		Resolved
[Row 3] AESTDAT [AESTDAT]		25-Jun-2018
[Row 3] AESTTIM [AESTTIM]		12:06
[Row 3] AEONGO [AEONGO]		No
[Row 3] AEENDAT [AEENDAT]		25-Jun-2018

Variable	Old Value	New Value
[Row 3] AEENTIM [AEENTIM]		13:15
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	27-Jun-2018 01:59 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	

Variable	Old Value	New Value
AEYN [AEYN]		Yes
[Row 1] AESPID [AESPID]		1
[Row 1] AETERM [AETERM]		CHEST DISCOMFORT
[Row 1] AESER [AESER]		No
[Row 1] AESEV [AESEV]		MILD
[Row 1] AEFREQ [AEFREQ]		Continuous
[Row 1] AEACN [AEACN]		No Action Taken
[Row 1] AECONTRT [AECONTRT]		No
[Row 1] AEDIS [AEDIS]		No
[Row 1] AEREL [AEREL]		Probably Related
[Row 1] AETEAE [AETEAE]		No
[Row 1] AEOUT [AEOUT]		Resolved
[Row 1] AESTDAT [AESTDAT]		25-Jun-2018
[Row 1] AESTTIM [AESTTIM]		10:55
[Row 1] AEONGO [AEONGO]		No
[Row 1] AEENDAT [AEENDAT]		25-Jun-2018
[Row 1] AEENTIM [AEENTIM]		11:08

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	29-Jun-2018 12:26 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 02:04 PM PDT (UTC-07:00)	Form marked as Not Complete
System	27-Jun-2018 01:59 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: All Visits
FORM: Adverse Events

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)	07-Aug-2018 02:11 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: All Visits
FORM: Adverse Events

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 3] AEDIS	Data Updated [29-Jun-2018 12:26 PM by (b) (6) vinceandassociates.com ((b) (6)	27-Jun-2018 02:04 PM	29-Jun-2018 12:26 PM
	Description			
	New: Answer is missing, please review **Old:** **By:** 27-Jun-2018 02:04 PM (b) (6) vinceandassociates.com ((b) (6)			

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: [CMQUANT]	
Form: [CMDOSFRM]	
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	
Unit: [CMTOTUN]	
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	

Start Time: [CMSTTIM]	
Time Unknown [CMSTTNK]	
End Date: [CMENDAT]	
End Time: [CMENTIM]	
Time Unknown [CMENTNK]	
Ongoing? [CMONGO]	

AUDIT TRAIL

VISIT: All Visits
FORM: Concomitant Medications

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	03-Jul-2018 10:03 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
CMYN [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 10:03 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: All Visits
FORM: Concomitant Medications

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	25-Oct-2018 11:23 AM PDT (UTC-07:00)	Form marked as "Form Monitored".
(b) (6) algopharm.com (b) (6) (b) (6)	11-Oct-2018 02:30 PM PDT (UTC-07:00)	Updated information (Form unmarked as "Form Monitored"). - ESignature
(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)	07-Aug-2018 02:11 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