Table of Contents

01-123 17

By Visit

- Screening 20
  - Visit Date 20
    - Data 20
    - Audit Trail 20
  - ICF 21
    - Data 21
    - Audit Trail 22
  - INCL/EXCL Criteria Summary 23
    - Data 23
    - Audit Trail 23
  - Demographics 25
    - Data 25
    - Audit Trail 25
  - Medical History 27
    - Data 27
    - Audit Trail 28
    - Query Log 30
  - Complete Physical Examination 31
    - Data 31
    - Audit Trail 34
  - Height, Weight and BMI 36
    - Data 36
    - Audit Trail 37
  - Serology Lab Evaluation 38
    - Data 38
    - Audit Trail 39
  - Serum Pregnancy Test 40
    - Data 40
    - Audit Trail 41
  - Vital Signs 42
    - Data 42
    - Audit Trail 44
  - UDS and Alcohol Laboratory Evaluation 47
    - Data 47
    - Audit Trail 47
  - Cotinine Evaluation 49
    - Data 49
    - Audit Trail 49
  - Chemistry Laboratory Evaluation 51
    - Data 51
    - Audit Trail 51

Table of Contents

Hematology Laboratory Evaluation 53
Data 53
Audit Trail 54
Urinalysis Laboratory Evaluation 55
Data 55
Audit Trail 56
Endocrinology Evaluation 57
Data 57
Audit Trail 58
Query Log 59
ECG Test Results 60
Data 60
Audit Trail 61
Female Contraceptive Method 63
Data 63
Audit Trail 64
Tobacco Use 65
Data 65
Audit Trail 69
Query Log 70
Day -1 72
Visit Date 72
Data 72
Audit Trail 72
Urine Pregnancy Test 73
Data 73
Audit Trail 74
Vital Signs 75
Data 75
Audit Trail 78
UDS and Alcohol Laboratory Evaluation 80
Data 80
Audit Trail 81
Symptom Directed Physical Exam 82
Data 82
Audit Trail 83
Day 1 84
Visit Date 84
Data 84
Audit Trail 84
Part A - Usual Brand Dose Log 85
Data 85
Audit Trail 87

Table of Contents

Part A - VLN Dosing Log 89
Data 89
Part A - Nicorette Dosing Log 90
Data 90
Randomization 91
Data 91
Audit Trail 92
Use Product Again - VAS 93
Data 93
Audit Trail 93
Day 2 95
Visit Date 95
Data 95
Audit Trail 95
Part A - Usual Brand Dose Log 96
Data 96
Part A - VLN Dosing Log 97
Data 97
Part A - Nicorette Dosing Log 98
Data 98
Audit Trail 99
Use Product Again - VAS 101
Data 101
Audit Trail 101
Day 3 102
Visit Date 102
Data 102
Audit Trail 103
Part A - Usual Brand Dose Log 104
Data 104
Part A - VLN Dosing Log 105
Data 105
Audit Trail 106
Part A - Nicorette Dosing Log 108
Data 108
Use Product Again - VAS 109
Data 109
Audit Trail 110
Day 4 111
Visit Date 111
Data 111
Audit Trail 111
Randomization 112

Data 112
Audit Trail 113
Part B - Controlled Nicorette Dosing Log-1 114
Data 114
Part B - Uncontrolled Nicorette Dosing Log 115
Data 115
Part B - Uncontrolled Usual Brand Dosing Log 116
Data 116
Part B - Controlled Usual Brand Dosing Log 117
Data 117
Part B - Controlled VLN Dosing Log 119
Data 119
Audit Trail 122
Part B - Uncontrolled VLN Dosing Log 126
Data 126
Audit Trail 129
1st Use - Tobacco/Nicotine Questionnaire 131
Data 131
Audit Trail 132
2nd Use - Tobacco/Nicotine Questionnaire 133
Data 133
Audit Trail 133
1st Use - Direct Effects of Product Questionnaire 134
Data 134
Audit Trail 135
2nd Use - Direct Effects of Product Questionnaire 136
Data 136
Audit Trail 137
1st Use - PK Blood Sampling 138
Data 138
Audit Trail 144
2nd Use - PK Blood Sampling 147
Data 147
Audit Trail 153
Use Product Again - VAS 1st use 157
Data 157
Audit Trail 157
Use Product Again - VAS 2nd use 158
Data 158
Audit Trail 159
Day 5 160
Visit Date 160
Data 160

Audit Trail 160
Part B - Controlled Nicorette Dosing Log 161
Data 161
Part B - Uncontrolled Nicorette Dosing Log 162
Data 162
Part B - Uncontrolled Usual Brand Dosing Log 163
Data 163
Audit Trail 167
Part B - Controlled Usual Brand Dosing Log 169
Data 169
Audit Trail 173
Part B - Controlled VLN Dosing Log 176
Data 176
Part B - Uncontrolled VLN Dosing Log 178
Data 178
1st Use - Tobacco/Nicotine Questionnaire 179
Data 179
Audit Trail 179
2nd Use - Tobacco/Nicotine Questionnaire 181
Data 181
Audit Trail 181
1st Use - Direct Effects of Product Questionnaire 182
Data 182
Audit Trail 183
2nd Use - Direct Effects of Product Questionnaire 184
Data 184
Audit Trail 184
1st Use - PK Blood Sampling 185
Data 185
Audit Trail 191
2nd Use - PK Blood Sampling 195
Data 195
Audit Trail 201
Use Product Again - VAS 1st use 205
Data 205
Audit Trail 205
Use Product Again - VAS 2nd use 206
Data 206
Audit Trail 206
Day 6 207
Visit Date 207
Data 207
Audit Trail 208

Table of Contents

Vital Signs 209
Data 209
Audit Trail 211
Chemistry Laboratory Evaluation 213
Data 213
Audit Trail 214
Hematology Laboratory Evaluation 215
Data 215
Audit Trail 216
Urinalysis Laboratory Evaluation 218
Data 218
Audit Trail 218
Symptom Directed Physical Exam 220
Data 220
Audit Trail 222
Query Log 224
Part B - Controlled Nicorette Dosing Log-1 224
Data 224
Audit Trail 225
Part B - Uncontrolled Nicorette Dosing Log 227
Data 227
Audit Trail 227
Part B - Controlled Usual Brand Dosing Log 229
Data 229
Part B - Uncontrolled Usual Brand Dosing Log 230
Data 230
Part B - Controlled VLN Dosing Log 231
Data 231
Part B - Uncontrolled VLN Dosing Log 233
Data 233
ECG Test Results 234
Data 234
Audit Trail 235
1st Use - Tobacco/Nicotine Questionnaire 237
Data 237
Audit Trail 237
2nd Use - Tobacco/Nicotine Questionnaire 238
Data 238
Audit Trail 239
1st Use - Direct Effects of Product Questionnaire 240
Data 240
Audit Trail 240
2nd Use - Direct Effects of Product Questionnaire 241

Data 241
Audit Trail 242
End of Study 243
Data 243
Audit Trail 244
1st Use - PK Blood Sampling 245
Data 245
Audit Trail 251
2nd Use - PK Blood Sampling 255
Data 255
Audit Trail 261
Use Product Again - VAS 1st use 264
Data 264
Audit Trail 265
Use Product Again - VAS 2nd use 266
Data 266
Audit Trail 266
Early Term 267
Visit Date 267
Data 267
Vital Signs 268
Data 268
Chemistry Laboratory Evaluation 269
Data 269
Hematology Laboratory Evaluation 271
Data 271
Urinalysis Laboratory Evaluation 272
Data 272
Symptom Directed Physical Exam 273
Data 273
ECG Test Results 274
Data 274
End of Study 276
Data 276
1st Use - PK Blood Sampling 277
Data 277
2nd Use - PK Blood Sampling 278
Data 278
All Visits 279
Adverse Events 279
Data 279
Audit Trail 285
Query Log 292

Concomitant Medications ... 296
Data ... 296
Audit Trail ... 300
Query Log ... 303
Unscheduled Visit ... 305
Unscheduled Vital Signs (25-Jun-2018) ... 305
Data ... 305
Audit Trail ... 307
By Domain
Visit Date ... 20
Screening ... 20
Data ... 20
Audit Trail ... 20
Day -1 ... 72
Data ... 72
Audit Trail ... 72
Day 1 ... 84
Data ... 84
Audit Trail ... 84
Day 2 ... 95
Data ... 95
Audit Trail ... 95
Day 3 ... 102
Data ... 102
Audit Trail ... 103
Day 4 ... 111
Data ... 111
Audit Trail ... 111
Day 5 ... 160
Data ... 160
Audit Trail ... 160
Day 6 ... 207
Data ... 207
Audit Trail ... 208
Early Term ... 267
Data ... 267
ICF ... 21
Screening ... 20
Data ... 21
Audit Trail ... 22
INCL/EXCL Criteria Summary ... 23
Screening ... 20
Data ... 23

Audit Trail 23
Demographics 25
Screening 20
Data 25
Audit Trail 25
Medical History 27
Screening 20
Data 27
Audit Trail 28
Query Log 30
Complete Physical Examination 31
Screening 20
Data 31
Audit Trail 34
Height, Weight and BMI 36
Screening 20
Data 36
Audit Trail 37
Serology Lab Evaluation 38
Screening 20
Data 38
Audit Trail 39
Serum Pregnancy Test 40
Screening 20
Data 40
Audit Trail 41
Vital Signs 42
Screening 20
Data 42
Audit Trail 44
Day -1 72
Data 75
Audit Trail 78
Day 6 207
Data 209
Audit Trail 211
Early Term 267
Data 268
UDS and Alcohol Laboratory Evaluation 47
Screening 20
Data 47
Audit Trail 47
Day -1 72

Data ... 80
Audit Trail ... 81
Cotinine Evaluation ... 49
Screening ... 20
Data ... 49
Audit Trail ... 49
Chemistry Laboratory Evaluation ... 51
Screening ... 20
Data ... 51
Audit Trail ... 51
Day 6 ... 207
Data ... 213
Audit Trail ... 214
Early Term ... 267
Data ... 269
Hematology Laboratory Evaluation ... 53
Screening ... 20
Data ... 53
Audit Trail ... 54
Day 6 ... 207
Data ... 215
Audit Trail ... 216
Early Term ... 267
Data ... 271
Urinalysis Laboratory Evaluation ... 55
Screening ... 20
Data ... 55
Audit Trail ... 56
Day 6 ... 207
Data ... 218
Audit Trail ... 218
Early Term ... 267
Data ... 272
Endocrinology Evaluation ... 57
Screening ... 20
Data ... 57
Audit Trail ... 58
Query Log ... 59
ECG Test Results ... 60
Screening ... 20
Data ... 60
Audit Trail ... 61
Day 6 ... 207

Data 234
Audit Trail 235
Early Term 267
Data 274
Female Contraceptive Method 63
Screening 20
Data 63
Audit Trail 64
Tobacco Use 65
Screening 20
Data 65
Audit Trail 69
Query Log 70
Urine Pregnancy Test 73
Day -1 72
Data 73
Audit Trail 74
Symptom Directed Physical Exam 82
Day -1 72
Data 82
Audit Trail 83
Day 6 207
Data 220
Audit Trail 222
Query Log 224
Early Term 267
Data 273
Part A - Usual Brand Dose Log 85
Day 1 84
Data 85
Audit Trail 87
Day 2 95
Data 96
Day 3 102
Data 104
Part A - VLN Dosing Log 89
Day 1 84
Data 89
Day 2 95
Data 97
Day 3 102
Data 105
Audit Trail 106

Table of Contents

Part A - Nicorette Dosing Log 90
Day 1 84
Data 90
Day 2 95
Data 98
Audit Trail 99
Day 3 102
Data 108
Randomization 91
Day 1 84
Data 91
Audit Trail 92
Day 4 111
Data 112
Audit Trail 113
Use Product Again - VAS 93
Day 1 84
Data 93
Audit Trail 93
Day 2 95
Data 101
Audit Trail 101
Day 3 102
Data 109
Audit Trail 110
Part B - Controlled Nicorette Dosing Log-1 114
Day 4 111
Data 114
Day 6 207
Data 224
Audit Trail 225
Part B - Uncontrolled Nicorette Dosing Log 115
Day 4 111
Data 115
Day 5 160
Data 162
Day 6 207
Data 227
Audit Trail 227
Part B - Uncontrolled Usual Brand Dosing Log 116
Day 4 111
Data 116
Day 5 160

Data 163
Audit Trail 167
Day 6 207
Data 230
Part B - Controlled Usual Brand Dosing Log 117
Day 4 111
Data 117
Day 5 160
Data 169
Audit Trail 173
Day 6 207
Data 229
Part B - Controlled VLN Dosing Log 119
Day 4 111
Data 119
Audit Trail 122
Day 5 160
Data 176
Day 6 207
Data 231
Part B - Uncontrolled VLN Dosing Log 126
Day 4 111
Data 126
Audit Trail 129
Day 5 160
Data 178
Day 6 207
Data 233
1st Use - Tobacco/Nicotine Questionnaire 131
Day 4 111
Data 131
Audit Trail 132
Day 5 160
Data 179
Audit Trail 179
Day 6 207
Data 237
Audit Trail 237
2nd Use - Tobacco/Nicotine Questionnaire 133
Day 4 111
Data 133
Audit Trail 133
Day 5 160

Data 181
Audit Trail 181
Day 6 207
Data 238
Audit Trail 239
1st Use - Direct Effects of Product Questionnaire 134
Day 4 111
Data 134
Audit Trail 135
Day 5 160
Data 182
Audit Trail 183
Day 6 207
Data 240
Audit Trail 240
2nd Use - Direct Effects of Product Questionnaire 136
Day 4 111
Data 136
Audit Trail 137
Day 5 160
Data 184
Audit Trail 184
Day 6 207
Data 241
Audit Trail 242
1st Use - PK Blood Sampling 138
Day 4 111
Data 138
Audit Trail 144
Day 5 160
Data 185
Audit Trail 191
Day 6 207
Data 245
Audit Trail 251
Early Term 267
Data 277
2nd Use - PK Blood Sampling 147
Day 4 111
Data 147
Audit Trail 153
Day 5 160
Data 195

Audit Trail 201
Day 6 207
Data 255
Audit Trail 261
Early Term 267
Data 278
Use Product Again - VAS 1st use 157
Day 4 111
Data 157
Audit Trail 157
Day 5 160
Data 205
Audit Trail 205
Day 6 207
Data 264
Audit Trail 265
Use Product Again - VAS 2nd use 158
Day 4 111
Data 158
Audit Trail 159
Day 5 160
Data 206
Audit Trail 206
Day 6 207
Data 266
Audit Trail 266
Part B - Controlled Nicorette Dosing Log 161
Day 5 160
Data 161
End of Study 243
Day 6 207
Data 243
Audit Trail 244
Early Term 267
Data 276
Adverse Events 279
All Visits 279
Data 279
Audit Trail 285
Query Log 292
Concomitant Medications 296
All Visits 279
Data 296

Audit Trail 300
Query Log 303
Unscheduled Vital Signs (25-Jun-2018) 305
Unscheduled Visit 305
Data 305
Audit Trail 307

Site:	Site A
Group:	Group A
Medrio ID:	0042
Subject Identifier:	01-123
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 10:35 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)	Enrolled	Completed
Subject ID	25-Jun-2018 08:54 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		01-123
Medrio ID	25-Jun-2018 08:54 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		42
Subject Status	25-Jun-2018 08:54 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Enrolled
Site	25-Jun-2018 08:54 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Site A
Group	25-Jun-2018 08:54 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Group A
ePRO Enabled	25-Jun-2018 08:54 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)
Unscheduled Visit	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]	19-Jun-2018

AUDIT TRAIL

VISIT: Screening
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:50 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		19-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 11:50 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-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	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:53 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]		19-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 11:53 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ICF

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)	08-Aug-2018 11:38 AM 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) algopharm.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) (b) (6) (b) (6)
Date/Time	25-Jun-2018 11:54 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 11:54 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-Jun-2018
Date of Birth: [DMBRTHDAT]	(b) (6)
Age: [DMAGE]	47
Age Unit: [DMAGEU]	YEARS
Gender: [DMSEX]	F
Ethnicity: [DMETHNIC]	NOT HISPANIC OR LATINO
Race: [DMRACE]	WHITE
Other, Specify: [DMRCOT]	

AUDIT TRAIL

VISIT: Screening
FORM: Demographics

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:55 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DMDAT [DMDAT]		19-Jun-2018
DMBRTHDAT [DMBRTHDAT]		(b) (6)
DMAGE [DMAGE]		47
DMAGEU [DMAGEU]		YEARS

Variable	Old Value	New Value
DMSEX [DMSEX]		F
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 11:55 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Demographics

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Demographics

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algopharm.com	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: Screening
FORM: Medical History

Does the subject have any relevant medical or surgical history (including drug allergies)? [MHYN]	Yes
Date of Visit: [MHDAT]	19-Jun-2018
Row 1	
Medical History #: [MHNUM]	1
Body System Code: [MHSCAT]	Psychiatric/Neurologic
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	HEADACHE - INTERMITTENT
Onset Date: [MHSTDAT]	UN-UNK-1987
Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	Yes
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) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:56 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
MHSMK [MHSMK]		Yes
MHRECUSE [MHRECUSE]		No
Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:56 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
MHYN [MHYN]		Yes
MHDAT [MHDAT]		19-Jun-2018
[Row 1] MHNUM [MHNUM]		1
[Row 1] MHSCAT [MHSCAT]		Psychiatric/Neurologic
[Row 1] MHCAT [MHSCAT]		HEADACHE - INTERMITTENT
[Row 1] MHSTDAT [MHSTDAT]		UN-UNK-1987
[Row 1] MHONGO [MHONGO]		Yes
[Row 1] MHCLSIG [MHCLSIG]		Not Clinically Sigficant

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 11:56 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 11:56 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 11:56 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Medical History

ID	Variable	Responses/Reasons	Opened	Closed
	MHRECUSE	Data Updated [25-Jun-2018 11:56 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	25-Jun-2018 11:56 AM	25-Jun-2018 11:56 AM
	Description			
	New: Data is missing, please review **Old:** **By:** 25-Jun-2018 11:56 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) (b) (6)			
	MHSMK	Data Updated [25-Jun-2018 11:56 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	25-Jun-2018 11:56 AM	25-Jun-2018 11:56 AM
	Description			
	New: Data is missing, please review **Old:** **By:** 25-Jun-2018 11:56 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) (b) (6)			

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) (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]	19-Jun-2018
Completion Time: [PETIM]	15:14
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) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:57 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN [PEYN]		Yes
PEDAT [PEDAT]		19-Jun-2018
PETIM [PETIM]		15:14
[Row 1] PETEST [PETEST]		GENERAL APPEARANCE
[Row 1] PEORRES [PEORRES]		NORMAL
[Row 2] PETEST [PETEST]		HEENT

Variable	Old Value	New Value
[Row 2] PEORRES [PEORRES]		NORMAL
[Row 3] PETEST [PETEST]		NECK/THYROID
[Row 3] PEORRES [PEORRES]		NORMAL
[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

User	Date/Time	Change
System	25-Jun-2018 11:57 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-Jun-2018
Height: [VSHGT]	168.0

Weight: [VSWGT]	81.1
BMI: [VSBMI]	28.7

AUDIT TRAIL

VISIT: Screening
FORM: Height, Weight and BMI

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:58 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSYN [VSYN]		Yes
VSDAT [VSDAT]		19-Jun-2018
VSHGT [VSHGT]		168.0
VSWGT [VSWGT]		81.1
VSBMI [VSBMI]		28.7

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 11:58 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Height, Weight and BMI

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Height, Weight and BMI

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

CLINICAL DATA

VISIT: Screening
FORM: Serology Lab Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	19-Jun-2018
Time of Collection: [LBTIM]	14:49
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 11:59 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN [LBYN]		Yes
LBDAT [LBDAT]		19-Jun-2018
LBTIM [LBTIM]		14:49
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 11:59 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Serology Lab Evaluation

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Serology Lab Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Serum Pregnancy Test

Was Serum Pregnancy Test performed? [LBHCGYN]	Yes
Date of collection: [LBDAT]	19-Jun-2018
Time of Collection: [LBTIM]	14:49
Time Unknown: [LBTMNK]	

AUDIT TRAIL

VISIT: Screening
FORM: Serum Pregnancy Test

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:00 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBHCGYN [LBHCGYN]		Yes
LBDAT1 [LBDAT]		19-Jun-2018
LBTIM1 [LBTIM]		14:49

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serum Pregnancy Test

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 12:00 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 11:55 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Serum Pregnancy Test

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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Serum Pregnancy Test

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

CLINICAL DATA

VISIT: Screening
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	14:35
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	19-Jun-2018
Time Taken: [VSTIM]	14:40
Time Unknown: [VSTMNK]	

Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.7
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	119
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	82
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	60
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	20
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) (b) (6) (b) (6)	
Date/Time	25-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]		No

Variable	Old Value	New Value
VSTIMS [VS1TIMS]		14:35
VS1DAT [VSDAT]		19-Jun-2018
VSTIM [VSTIM]		14:40
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.7
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		119
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		82
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		60
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		20

Variable	Old Value	New Value
[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 12:01 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-Jun-2018
Time of Collection: [LBTIM]	14:22
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:02 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		19-Jun-2018
LBTIM3 [LBTIM]		14:22
LBNRIND3		Yes

Variable	Old Value	New Value
[LBNRIND]		

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 12:02 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-Jun-2018
Time of Collection: [LBTIM]	14:22
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) [redacted] vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:02 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN4 [LBYN]		Yes
LBDAT4 [LBDAT]		19-Jun-2018
LBTIM4 [LBTIM]		14:22
LBNRIND4		No

Variable	Old Value	New Value
[LBNRIND]		
[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 12:02 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-Jun-2018
Time of Collection: [LBTIM]	14:49
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:02 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		19-Jun-2018
LBTIM5 [LBTIM]		14:49

Variable	Old Value	New Value
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 12:02 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-Jun-2018
Time of Collection: [LBTIM]	14:49
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	No
Row 1	
Test Name: [LBTEST]	HEMATOCRIT
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS
Row 2	
Test Name: [LBTEST]	HEMOGLOBIN
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS

AUDIT TRAIL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

Logged in User	[redacted] vinceandassociates.com [redacted]	
Date/Time	25-Jun-2018 12:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		19-Jun-2018
LBTIM6 [LBTIM]		14:49
LBNRIND6 [LBNRIND]		No
[Row 1] LBTEST6 [LBTEST]		HEMATOCRIT
[Row 1] LBCLSIG6 [LBCLSIG]		NCS
[Row 2] LBTEST6 [LBTEST]		HEMOGLOBIN
[Row 2] LBCLSIG6 [LBCLSIG]		NCS

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 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	19-Jun-2018
Time of Collection: [LBTIM]	14:22
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		19-Jun-2018
LBTIM7 [LBTIM]		14:22
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 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	No
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]	

AUDIT TRAIL

VISIT: Screening
FORM: Endocrinology Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:04 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN5 [LBYN]		No

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Endocrinology Evaluation

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	11-Sep-2018 11:56 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 12:04 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 12:04 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 11:55 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Endocrinology 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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Endocrinology Evaluation

ID	Variable	Responses/Reasons	Opened	Closed
	LBYN5	NOT APPLICABLE FOR THIS SUBJECT. [25-Jun-2018 12:04 PM by (b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6) Response satisfies query [11-Sep-2018 11:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	25-Jun-2018 12:04 PM	11-Sep-2018 11:56 AM
	Description			
	New: Laboratory assessment was not performed as specified in the protocol; please clarify **Old:** **By:** 25-Jun-2018 12:04 PM (b) (6)@algopharm.com (b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: Endocrinology 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: ECG Test Results

Was the ECG performed? [EGYN]	Yes
Date: [EGDAT]	19-Jun-2018
Visit: [EGVIS]	Screening
Row 1	
Time: [EGTIM]	14:32
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	54
PR Interval: [EGPR]	122
QRS Interval: [EGQRS]	99
QT Interval: [EGQT]	410
QTcB Interval: [EGQTCB]	389

QTcF: [EGQTCF]	396
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:05 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT [EGDAT]		19-Jun-2018
EGVIS [EGVIS]		Screening
[Row 1] EG1TIM [EGTIM]		14:32
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		54
[Row 1] EG1PR [EGPR]		122
[Row 1] EG1QRS [EGQRS]		99
[Row 1] EG1QT [EGQT]		410
[Row 1] EGQTCB [EGQTCB]		389
[Row 1] EG1QTCF [EGQTCF]		396
[Row 1] EG1CLSIG		NORMAL

Variable	Old Value	New Value
[EGCLSIG]		

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 12:05 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ECG Test Results

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 11:38 AM 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) algopharm.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]	19-Jun-2018
Childbearing Potential: [SCSTATUS]	CHILDBEARING POTENTIAL
Is subject considered post-menopausal? [SCPOST]	
Last menses: [SCMENDAT]	

Row 1	
Please select the contraceptive method used by subject: [SCTEST]	CONDOM WITH SPERMICIDE
Start Date: [SCSTDAT]	19-Jun-2018

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

AUDIT TRAIL

VISIT: Screening
FORM: Female Contraceptive Method

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:06 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SCDAT [SCDAT]		19-Jun-2018
SC1STATUS [SCSTATUS]		CHILDBEARING POTENTIAL
[Row 1] SC1TEST [SCTEST]		CONDOM WITH SPERMICIDE
[Row 1] SCSTDAT [SCSTDAT]		19-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Female Contraceptive Method

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 12:06 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 11:55 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Female Contraceptive Method

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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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-1985
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	

Daily Use: [SUDYUS]	12
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)	
Date/Time	11-Jul-2018 11:22 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-1985
[Row 1] SUDYUS1 [SUDYUS]		12
[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 [SUFRQ]		Never
[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

Variable	Old Value	New Value
[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 11:22 AM PDT (UTC-07:00)	Form marked as Not Complete
System	11-Jul-2018 11:22 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 08:40 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Tobacco Use

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:38 AM 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 11:22 AM by (b) (6) vinceandass	11-Jul-2018 11:22 AM	16-Jul-2018 09:21 AM

ID	Variable	Responses/Reasons	Opened	Closed
		ociates.com ([redacted] Response satisfies query [16-Jul-2018 09:21 AM by [redacted] vinceandassociates.com ([redacted] [redacted]		
	Description			
	New: Yearly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:22 AM [redacted] vinceandassociates.com ([redacted]			
	[Row 1] SUWKUS1	NOT APPLICABLE [11-Jul-2018 11:23 AM by [redacted] vinceandassociates.com ([redacted] Response satisfies query [16-Jul-2018 09:21 AM by [redacted] vinceandassociates.com ([redacted] [redacted]	11-Jul-2018 11:22 AM	16-Jul-2018 09:21 AM
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:22 AM [redacted] vinceandassociates.com ([redacted]			
	[Row 1] SUMONUS1	NOT APPLICABLE [11-Jul-2018 11:23 AM by [redacted] vinceandassociates.com ([redacted] Response satisfies query [16-Jul-2018 09:21 AM by [redacted] vinceandassociates.com ([redacted] [redacted]	11-Jul-2018 11:22 AM	16-Jul-2018 09:21 AM
	Description			
	New: Monthly Use is missing, please review			

ID	Variable	Responses/Reasons	Opened	Closed
	Old: **By:** 11-Jul-2018 11:22 AM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: Tobacco 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 -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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:17 PM 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 12:17 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day -1
FORM: Urine Pregnancy Test

Was Urine Pregnancy Test performed? [LBHCGYN]	Yes

Date of collection: [LBDAT]	22-Jun-2018
Time of Collection: [LBTIM]	08:57
Time Unknown: [LBTMNK]	

AUDIT TRAIL

VISIT: Day -1
FORM: Urine Pregnancy Test

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:18 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBHCGYN1 [LBHCGYN]		Yes
LBDAT2 [LBDAT]		22-Jun-2018
LBTIM2 [LBTIM]		08:57

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Urine Pregnancy Test

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 12:18 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 11:55 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Urine Pregnancy Test

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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Urine 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: Day -1
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	07:57
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	22-Jun-2018

Time Taken: [VSTIM]	08:02
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]	155
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	OUT-OF-RANGE, ABNORMAL NCS
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	101

Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	OUT-OF-RANGE, ABNORMAL NCS
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	73
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 -1
FORM: Vital Signs

Logged in User	[redacted] vinceandassociates.com [redacted]	
Date/Time	25-Jun-2018 12:21 PM 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]		07:57
VS1DAT [VSDAT]		22-Jun-2018
VSTIM [VSTIM]		08:02
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.5
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		155
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		OUT-OF-RANGE, ABNORMAL NCS
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		101
[Row 3] VSORRESU [VSORRESU]		mmHg

Variable	Old Value	New Value
[Row 3] VSCLSIG [VSCLSIG]		OUT-OF-RANGE, ABNORMAL NCS
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		73
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		14
[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 12:21 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Vital Signs

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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Vital Signs

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

CLINICAL DATA

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

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	22-Jun-2018
Time of Collection: [LBTIM]	08:57
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:24 PM 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]		08:57
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 12:24 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:38 AM 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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:24 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 -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 12:24 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

VISIT: Day 1
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:25 PM 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

User	Date/Time	Change
System	25-Jun-2018 12:25 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Visit Date

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

CLINICAL DATA

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

AD LIB USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG	
Date of Visit: [EXDAT]	23-Jun-2018

Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:00
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:06
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:16
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:22
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:32
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:39

Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:06
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:12

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 09:02 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		23-Jun-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM [EXTIM]		09:00
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		09:06
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1
[Row 2] EXTIM [EXTIM]		09:16

Variable	Old Value	New Value
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		09:22
[Row 3] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		10:32
[Row 3] EXCIGRET [EXCIGRET]		1
[Row 3] EXTIMRET [EXTIMRET]		10:39
[Row 4] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		12:06
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		12:12

FORM STATUS CHANGE LOG

VISIT: Day 1
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 09:02 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
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 08:09 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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]	
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 - VLN Dosing Log

User	Date/Time	Change
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG	
Date of Visit: [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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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) 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: Randomization

Date of Randomization: [DSRDAT]	23-Jun-2018
Randomization Number: [DSNUM]	1035
Sequence Group [DSRNGRP]	BCA

AUDIT TRAIL

VISIT: Day 1
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 11:20 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 08:54 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]		1035
DSRNGRP [DSRNGRP]		BCA

FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Randomization

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Randomization

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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) (b) (6) (b) (6)
Date/Time	25-Jun-2018 12:25 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 1
FORM: Use Product Again - VAS

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 12:25 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

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

CLINICAL DATA

VISIT: Day 2
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	24-Jun-2018

AUDIT TRAIL

VISIT: Day 2
FORM: Visit Date

Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:25 PM 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 12:25 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 11:38 AM 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) 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 - Usual Brand Dose Log

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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 - 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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]	24-Jun-2018

Row 1	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:00
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	09:08
Row 2	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:54
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	13:00

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 08:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT2 [EXDAT]		24-Jun-2018
[Row 1] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)

Variable	Old Value	New Value
[Row 1] EXDSPD2 [EXDSPD]		1
[Row 1] EXTIM2 [EXTIM]		09:00
[Row 1] EXNICRET [EXNICRET]		1
[Row 1] EXTIMRET2 [EXTIMRET]		09:08
[Row 2] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 2] EXDSPD2 [EXDSPD]		1
[Row 2] EXTIM2 [EXTIM]		12:54
[Row 2] EXNICRET [EXNICRET]		1
[Row 2] EXTIMRET2 [EXTIMRET]		13:00

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	26-Jun-2018 08:40 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
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)	02-Aug-2018 08:10 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) 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: 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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:25 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 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 12:25 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 08:30 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 08:30 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:54 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]	25-Jun-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:00
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:05
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1

Time Dispensed: [EXTIM]	10:41
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:46
Row 3	
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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 09:21 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT1 [EXDAT]		25-Jun-2018
[Row 1] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD1 [EXDSPD]		1
[Row 1] EXTIM1 [EXTIM]		09:00
[Row 1] EXCIGRET1 [EXCIGRET]		1
[Row 1] EXTIMRET1		09:05

Variable	Old Value	New Value
[EXTIMRET]		
[Row 2] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD1 [EXDSPD]		1
[Row 2] EXTIM1 [EXTIM]		10:41
[Row 2] EXCIGRET1 [EXCIGRET]		1
[Row 2] EXTIMRET1 [EXTIMRET]		10:46
[Row 3] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD1 [EXDSPD]		1
[Row 3] EXTIM1 [EXTIM]		12:49
[Row 3] EXCIGRET1 [EXCIGRET]		1
[Row 3] EXTIMRET1 [EXTIMRET]		12:55

FORM STATUS CHANGE LOG

VISIT: Day 3
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 09:21 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
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 08:11 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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]	
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 3
FORM: Part A - Nicorette Dosing Log

User	Date/Time	Change
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 3
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 3
FORM: Use Product Again - VAS

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	26-Jun-2018 08:31 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 3
FORM: Use Product Again - VAS

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	26-Jun-2018 08:31 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
FORM: Use Product Again - VAS

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted] [redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	08-Aug-2018 11:38 AM 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

User	Date/Time	Change
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 4
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day 4
FORM: Randomization

Date of Randomization: [DSRDAT]	26-Jun-2018
Randomization Number: [DSNUM]	2034
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 12:35 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		26-Jun-2018
DSRNUM [DSNUM]		2034
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 12:35 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	
Row 1	
Product: [EXPRDB]	
Session Start Time: [EXSRTTIMB]	
Session End Time: [EXENTMB]	
Did the subject consume any beverages during controlled product use?: [EXBEV]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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) 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 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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]	09:00
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:00:00
Puff End: [EXPFEN]	09:00:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	09:00:30
Puff End: [EXPFEN]	09:00:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:01:00
Puff End: [EXPFEN]	09:01:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:01:30
Puff End: [EXPFEN]	09:01:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:02:00
Puff End: [EXPFEN]	09:02:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:02:30
Puff End: [EXPFEN]	09:02:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:03:00
Puff End: [EXPFEN]	09:03:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:03:30
Puff End: [EXPFEN]	09:03:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:04:00
Puff End: [EXPFEN]	09:04:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 10	
Puff: [EXPFF]	Puff 10
Puff Begin: [EXPFBG]	09:04:30
Puff End: [EXPFEN]	09:04:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
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 12:51 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATVLN		26-Jun-2018

Variable	Old Value	New Value
[EXDATVLN]		
EXSTTIM [EXSTTIM]		09:00
[Row 1] EXPFF [EXPFF]		Puff 1
[Row 1] EXPFBG [EXPFBG]		09:00:00
[Row 1] EXPFEN [EXPFEN]		09:00:03
[Row 1] EXMISPF [EXMISPF]		No
[Row 2] EXPFF [EXPFF]		Puff 2
[Row 2] EXPFBG [EXPFBG]		09:00:30
[Row 2] EXPFEN [EXPFEN]		09:00:33
[Row 2] EXMISPF [EXMISPF]		No
[Row 3] EXPFF [EXPFF]		Puff 3
[Row 3] EXPFBG [EXPFBG]		09:01:00
[Row 3] EXPFEN [EXPFEN]		09:01:03
[Row 3] EXMISPF [EXMISPF]		No
[Row 4] EXPFF [EXPFF]		Puff 4
[Row 4] EXPFBG [EXPFBG]		09:01:30
[Row 4] EXPFEN [EXPFEN]		09:01:33
[Row 4] EXMISPF [EXMISPF]		No
[Row 5] EXPFF [EXPFF]		Puff 5
[Row 5] EXPFBG [EXPFBG]		09:02:00
[Row 5] EXPFEN [EXPFEN]		09:02:03
[Row 5] EXMISPF [EXMISPF]		No

Variable	Old Value	New Value
[Row 6] EXPFF [EXPFF]		Puff 6
[Row 6] EXPFBG [EXPFBG]		09:02:30
[Row 6] EXPFEN [EXPFEN]		09:02:33
[Row 6] EXMISPF [EXMISPF]		No
[Row 7] EXPFF [EXPFF]		Puff 7
[Row 7] EXPFBG [EXPFBG]		09:03:00
[Row 7] EXPFEN [EXPFEN]		09:03:03
[Row 7] EXMISPF [EXMISPF]		No
[Row 8] EXPFF [EXPFF]		Puff 8
[Row 8] EXPFBG [EXPFBG]		09:03:30
[Row 8] EXPFEN [EXPFEN]		09:03:33
[Row 8] EXMISPF [EXMISPF]		No
[Row 9] EXPFF [EXPFF]		Puff 9
[Row 9] EXPFBG [EXPFBG]		09:04:00
[Row 9] EXPFEN [EXPFEN]		09:04:03
[Row 9] EXMISPF [EXMISPF]		No
[Row 10] EXPFF [EXPFF]		Puff 10
[Row 10] EXPFBG [EXPFBG]		09:04:30
[Row 10] EXPFEN [EXPFEN]		09:04:33
[Row 10] EXMISPF [EXMISPF]		No
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 12:51 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:35 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:12 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]	15:00
Session End Time: [EXENDTIM]	15:02
Row 1	
Inhalation Begin: [EXINHBG]	15:00:01
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:00:02
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:00:10
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:00:12
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:00:51

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:00:52
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:01:15
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:01:16
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:01:29
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:01:31
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:01:46
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:01:48
Time Unknown: [EXTIMUNK]	

Row 7	
Inhalation Begin: [EXINHBG]	15:02:01
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:02:02
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:02:25
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:02:26
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:02:42
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:02:43
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:02:57
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:02:58

Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	10

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 12:53 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]		15:00
EX9ENDTIM [EXENDTIM]		15:02
[Row 1] EX9INHBG [EXINHBG]		15:00:01
[Row 1] EX9INEN [EXINEN]		15:00:02
[Row 2] EX9INHBG [EXINHBG]		15:00:10
[Row 2] EX9INEN [EXINEN]		15:00:12
[Row 3] EX9INHBG [EXINHBG]		15:00:51
[Row 3] EX9INEN [EXINEN]		15:00:52
[Row 4] EX9INHBG [EXINHBG]		15:01:15
[Row 4] EX9INEN [EXINEN]		15:01:16
[Row 5] EX9INHBG [EXINHBG]		15:01:29

Variable	Old Value	New Value
[Row 5] EX9INEN [EXINEN]		15:01:31
[Row 6] EX9INHBG [EXINHBG]		15:01:46
[Row 6] EX9INEN [EXINEN]		15:01:48
[Row 7] EX9INHBG [EXINHBG]		15:02:01
[Row 7] EX9INEN [EXINEN]		15:02:02
[Row 8] EX9INHBG [EXINHBG]		15:02:25
[Row 8] EX9INEN [EXINEN]		15:02:26
[Row 9] EX9INHBG [EXINHBG]		15:02:42
[Row 9] EX9INEN [EXINEN]		15:02:43
[Row 10] EX9INHBG [EXINHBG]		15:02:57
[Row 10] EX9INEN [EXINEN]		15:02:58
EX9BEVB [EXBEVB]		No
EX9INTOT [EXINTOT]		10

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 12:53 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:35 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:12 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 10:28 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 10:28 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 10:28 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 10:28 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 10:28 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 10:28 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 10:28 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 10:28 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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]	08-Aug-2018 11:38 AM 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]	08:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:02

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:06
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]	09:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:16
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]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:31
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]	09:45

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:01
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]	10:31
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]	11:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	11:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	12:00
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 10:25 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]		08:55
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		26-Jun-2018
[Row 2] PKTIM [PKTIM]		09:02
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		26-Jun-2018
[Row 3] PKTIM [PKTIM]		09:06
[Row 3] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		26-Jun-2018
[Row 4] PKTIM [PKTIM]		09:07
[Row 5] PKTPT [PKTPT]		10 minute

Variable	Old Value	New Value
[Row 5] PKDAT [PKDAT]		26-Jun-2018
[Row 5] PKTIM [PKTIM]		09:10
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		26-Jun-2018
[Row 6] PKTIM [PKTIM]		09:12
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		26-Jun-2018
[Row 7] PKTIM [PKTIM]		09:16
[Row 7] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		26-Jun-2018
[Row 8] PKTIM [PKTIM]		09:20
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		26-Jun-2018
[Row 9] PKTIM [PKTIM]		09:31
[Row 9] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		26-Jun-2018
[Row 10] PKTIM [PKTIM]		09:45
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		26-Jun-2018

Variable	Old Value	New Value
[Row 11] PKTIM [PKTIM]		10:01
[Row 11] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		26-Jun-2018
[Row 12] PKTIM [PKTIM]		10:31
[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]		11:00
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		26-Jun-2018
[Row 14] PKTIM [PKTIM]		11:30
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		26-Jun-2018
[Row 15] PKTIM [PKTIM]		12:00

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 10:25 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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]	14:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:06
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]	15:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:31

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]	15:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:01
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]	16:33
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]	17:04
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	17:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	18:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection

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 10:27 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]		14:55
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		26-Jun-2018
[Row 2] PKTIM1		15:02

Variable	Old Value	New Value
[PKTIM]		
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		26-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:06
[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]		15:07
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		26-Jun-2018
[Row 5] PKTIM1 [PKTIM]		15:10
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		26-Jun-2018
[Row 6] PKTIM1 [PKTIM]		15:12
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		26-Jun-2018
[Row 7] PKTIM1 [PKTIM]		15:15
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		26-Jun-2018
[Row 8] PKTIM1 [PKTIM]		15:20
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		26-Jun-2018

Variable	Old Value	New Value
[Row 9] PKTIM1 [PKTIM]		15:31
[Row 9] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		26-Jun-2018
[Row 10] PKTIM1 [PKTIM]		15:45
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		26-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:01
[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]		16:33
[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]		17:04
[Row 13] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		26-Jun-2018
[Row 14] PKTIM1 [PKTIM]		17:30
[Row 15] PKTPT1 [PKTPT]		180 minute

Variable	Old Value	New Value
[Row 15] PKDAT1 [PKDAT]		26-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:11
[Row 15] PKCODE1 [PKCODE]		A - Late due to difficult collection

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 10:27 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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	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: 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 10:13 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 10:13 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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".
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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	28-Jun-2018 10:14 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 10:14 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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) 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: 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 10:12 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 10:12 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 5
FORM: Visit Date

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

CLINICAL DATA

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

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	

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
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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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]	15:01
Session End Time: [EXENDTIM]	15:06

Row 1	
Inhalation Begin: [EXINHBG]	15:01:09
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:01:10
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:01:21
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:01:22
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:01:43
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:01:44
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:02:04
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:02:05

Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:02:24
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:02:25
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:02:44
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:02:45
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:03:13
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:03:14
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:03:46
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	15:03:47
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:04:34
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:04:35
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:05:24
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:05:26
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	15:06:09
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:06:10
Time Unknown: [EXTIMUNK]	

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

Session Total Inhalations: [EXINTOT]	11

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 11:19 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATB [EXDATB]		27-Jun-2018
EXSRTTIM [EXSRTTIM]		15:01
EXENDTIM [EXENDTIM]		15:06
[Row 1] EXINHBG [EXINHBG]		15:01:09
[Row 1] EXINEN [EXINEN]		15:01:10
[Row 2] EXINHBG [EXINHBG]		15:01:21
[Row 2] EXINEN [EXINEN]		15:01:22
[Row 3] EXINHBG [EXINHBG]		15:01:43
[Row 3] EXINEN [EXINEN]		15:01:44
[Row 4] EXINHBG [EXINHBG]		15:02:04
[Row 4] EXINEN [EXINEN]		15:02:05
[Row 5] EXINHBG [EXINHBG]		15:02:24
[Row 5] EXINEN [EXINEN]		15:02:25
[Row 6] EXINHBG [EXINHBG]		15:02:44
[Row 6] EXINEN [EXINEN]		15:02:45
[Row 7] EXINHBG		15:03:13

Variable	Old Value	New Value
[EXINHBG]		
[Row 7] EXINEN [EXINEN]		15:03:14
[Row 8] EXINHBG [EXINHBG]		15:03:46
[Row 8] EXINEN [EXINEN]		15:03:47
[Row 9] EXINHBG [EXINHBG]		15:04:34
[Row 9] EXINEN [EXINEN]		15:04:35
[Row 10] EXINHBG [EXINHBG]		15:05:24
[Row 10] EXINEN [EXINEN]		15:05:26
[Row 11] EXINHBG [EXINHBG]		15:06:09
[Row 11] EXINEN [EXINEN]		15:06:10
EXBEVB [EXBEVB]		No
EXINTOT [EXINTOT]		11

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	28-Jun-2018 11:19 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:35 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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)	02-Aug-2018 08:13 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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]	09:01

Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:01:30
Puff End: [EXPFEN]	09:01:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	09:02:00
Puff End: [EXPFEN]	09:02:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:02:30
Puff End: [EXPFEN]	09:02:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:03:00
Puff End: [EXPFEN]	09:03:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:03:30
Puff End: [EXPFEN]	09:03:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:04:00
Puff End: [EXPFEN]	09:04:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:04:30
Puff End: [EXPFEN]	09:04:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:05:01
Puff End: [EXPFEN]	09:05:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:05:30
Puff End: [EXPFEN]	09:05:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 10	
Puff: [EXPFF]	Puff 10
Puff Begin: [EXPFBG]	09:06:00
Puff End: [EXPFEN]	09:06:03
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 11:16 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX8DATVLN [EXDATVLN]		27-Jun-2018
EX8STTIM [EXSTTIM]		09:01
[Row 1] EX8PFF [EXPFF]		Puff 1
[Row 1] EX8PFBG [EXPFBG]		09:01:30
[Row 1] EX8PFEN [EXPFEN]		09:01:33
[Row 1] EX8MISPF [EXMISPF]		No
[Row 2] EX8PFF [EXPFF]		Puff 2
[Row 2] EX8PFBG		09:02:00

Variable	Old Value	New Value
[EXPFBG]		
[Row 2] EX8PFEN [EXPFEN]		09:02:03
[Row 2] EX8MISPF [EXMISPF]		No
[Row 3] EX8PFF [EXPFF]		Puff 3
[Row 3] EX8PFBG [EXPFBG]		09:02:30
[Row 3] EX8PFEN [EXPFEN]		09:02:33
[Row 3] EX8MISPF [EXMISPF]		No
[Row 4] EX8PFF [EXPFF]		Puff 4
[Row 4] EX8PFBG [EXPFBG]		09:03:00
[Row 4] EX8PFEN [EXPFEN]		09:03:03
[Row 4] EX8MISPF [EXMISPF]		No
[Row 5] EX8PFF [EXPFF]		Puff 5
[Row 5] EX8PFBG [EXPFBG]		09:03:30
[Row 5] EX8PFEN [EXPFEN]		09:03:33
[Row 5] EX8MISPF [EXMISPF]		No
[Row 6] EX8PFF [EXPFF]		Puff 6
[Row 6] EX8PFBG [EXPFBG]		09:04:00
[Row 6] EX8PFEN [EXPFEN]		09:04:03
[Row 6] EX8MISPF [EXMISPF]		No
[Row 7] EX8PFF [EXPFF]		Puff 7
[Row 7] EX8PFBG [EXPFBG]		09:04:30
[Row 7] EX8PFEN [EXPFEN]		09:04:33

Variable	Old Value	New Value
[Row 7] EX8MISPF [EXMISPF]		No
[Row 8] EX8PFF [EXPFF]		Puff 8
[Row 8] EX8PFBG [EXPFBG]		09:05:01
[Row 8] EX8PFEN [EXPFEN]		09:05:04
[Row 8] EX8MISPF [EXMISPF]		No
[Row 9] EX8PFF [EXPFF]		Puff 9
[Row 9] EX8PFBG [EXPFBG]		09:05:30
[Row 9] EX8PFEN [EXPFEN]		09:05:33
[Row 9] EX8MISPF [EXMISPF]		No
[Row 10] EX8PFF [EXPFF]		Puff 10
[Row 10] EX8PFBG [EXPFBG]		09:06:00
[Row 10] EX8PFEN [EXPFEN]		09:06:03
[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 11:16 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:35 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:54 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 08:14 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

Was Questionnaire performed at all time points: [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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 10:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF [QSPERF]		Yes

Variable	Old Value	New Value
QSUSE [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 10:49 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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
(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)	08-Aug-2018 11:38 AM 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 10:49 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 10:49 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 10:49 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 10:49 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 10:49 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 10:49 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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
(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)	08-Aug-2018 11:38 AM 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]	08:56
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	Yes
Time Unknown [PKACTNK]	
Comments: [PKCODE]	D - No Sample Collected due to difficult collection
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:06

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	Yes
Time Unknown [PKACTNK]	
Comments: [PKCODE]	D - No Sample Collected due to difficult collection
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:13
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:16
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:38
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:46
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:06

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:34
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	11:03
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 14	
Timepoint: [PKTPT]	150 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	11:31
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	12:01
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) (b) (6)	
Date/Time	17-Aug-2018 12:25 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 1] PKCODE [PKCODE]		A - Late due to difficult collection

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 10:38 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]		08:56
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKSTAT [PKSTAT]		Yes
[Row 2] PKCODE [PKCODE]		D - No Sample Collected due to difficult collection
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		27-Jun-2018
[Row 3] PKTIM [PKTIM]		09:06
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKSTAT [PKSTAT]		Yes
[Row 4] PKCODE [PKCODE]		D - No Sample Collected due to difficult collection
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		27-Jun-2018
[Row 5] PKTIM [PKTIM]		09:11
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		27-Jun-2018
[Row 6] PKTIM [PKTIM]		09:13

Variable	Old Value	New Value
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		27-Jun-2018
[Row 7] PKTIM [PKTIM]		09:16
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		27-Jun-2018
[Row 8] PKTIM [PKTIM]		09:21
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		27-Jun-2018
[Row 9] PKTIM [PKTIM]		09:38
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		27-Jun-2018
[Row 10] PKTIM [PKTIM]		09:46
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		27-Jun-2018
[Row 11] PKTIM [PKTIM]		10:06
[Row 11] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		27-Jun-2018
[Row 12] PKTIM [PKTIM]		10:34
[Row 12] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 13] PKTPT [PKTPT]		120 minute

Variable	Old Value	New Value
[Row 13] PKDAT [PKDAT]		27-Jun-2018
[Row 13] PKTIM [PKTIM]		11:03
[Row 13] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		27-Jun-2018
[Row 14] PKTIM [PKTIM]		11:31
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		27-Jun-2018
[Row 15] PKTIM [PKTIM]		12:01

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 10:38 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	19-Sep-2018 02:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".
klove-johnson@vinceandassociates.com (b) (6) (b) (6)	17-Aug-2018 12:24 PM PDT (UTC-07:00)	Updated information (Form partially unmarked as "Form Monitored").(PKCODE [1])
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:38 AM 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) 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: 2nd Use - PK Blood Sampling

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	14:59
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection

Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:04
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:10
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:13
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	27-Jun-2018

Time: [PKTIM]	15:16
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:33
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection

Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:53
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:36
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	17:01
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	17:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	C - Early Collection; please specify in Lab Note
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	27-Jun-2018

Time: [PKTIM]	18:01
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 10:45 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]		14:59
[Row 1] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		27-Jun-2018
[Row 2] PKTIM1 [PKTIM]		15:04
[Row 2] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		27-Jun-2018

Variable	Old Value	New Value
[Row 3] PKTIM1 [PKTIM]		15:07
[Row 3] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		27-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:10
[Row 4] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		27-Jun-2018
[Row 5] PKTIM1 [PKTIM]		15:11
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		27-Jun-2018
[Row 6] PKTIM1 [PKTIM]		15:13
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		27-Jun-2018
[Row 7] PKTIM1 [PKTIM]		15:16
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		27-Jun-2018
[Row 8] PKTIM1 [PKTIM]		15:21
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		27-Jun-2018
[Row 9] PKTIM1 [PKTIM]		15:33

Variable	Old Value	New Value
[Row 9] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		27-Jun-2018
[Row 10] PKTIM1 [PKTIM]		15:53
[Row 10] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		27-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:05
[Row 11] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		27-Jun-2018
[Row 12] PKTIM1 [PKTIM]		16:36
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		27-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:01
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		27-Jun-2018
[Row 14] PKTIM1 [PKTIM]		17:30
[Row 14] PKCODE1 [PKCODE]		C - Early Collection; please specify in Lab Note
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		27-Jun-2018

Variable	Old Value	New Value
[Row 15] PKTIM1 [PKTIM]		18:01

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 10:45 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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 10:13 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 10:13 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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".

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)	08-Aug-2018 11:38 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 10:13 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 10:13 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:38 AM 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	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	28-Jun-2018 11:20 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 11:20 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
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)	08-Aug-2018 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day 6
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	18:11
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	28-Jun-2018
Time Taken: [VSTIM]	18:16
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	37.1
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]	81
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	66
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	12
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 01:52 PM 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]		18:11
VS1DAT [VSDAT]		28-Jun-2018
VSTIM [VSTIM]		18:16
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		37.1
[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]		115
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		81
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		66
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		12
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: 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 01:52 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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]	18:01
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 10:07 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]		18:01
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 10:07 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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]	18:01
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	No

Row 1	
Test Name: [LBTEST]	HEMATOCRIT
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS
Row 2	
Test Name: [LBTEST]	HEMOGLOBIN
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS

AUDIT TRAIL

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 10:07 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
LBTIM6 [LBTIM]	06:35	18:01
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 10:07 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]		06:35
LBNRIND6 [LBNRIND]		No

Variable	Old Value	New Value
[Row 1] LBTEST6 [LBTEST]		HEMATOCRIT
[Row 1] LBCLSIG6 [LBCLSIG]		NCS
[Row 2] LBTEST6 [LBTEST]		HEMOGLOBIN
[Row 2] LBCLSIG6 [LBCLSIG]		NCS

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 10:07 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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) 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: Urinalysis Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	28-Jun-2018
Time of Collection: [LBTIM]	06:35
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 10:07 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]		06:35
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 10:07 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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) 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: Symptom Directed Physical Exam

Was physical examination performed? [PEYN]	Yes
Examination Date: [PEDAT]	28-Jun-2018
Completion Time: [PTIM]	18:26
ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM	
Row 1	
Body System Examined: [PETEST]	General Appearance
Not done: [PESTAT]	No
Examination Results: [PEORRES]	Normal
Abnormal Findings: [PECLSIG]	
Row 2	
Body System Examined: [PETEST]	Respiratory
Not done: [PESTAT]	No

Examination Results: [PEORRES]	Normal
Abnormal Findings: [PECLSIG]	
Row 3	
Body System Examined: [PETEST]	Cardiovascular
Not done: [PESTAT]	No
Examination Results: [PEORRES]	Normal
Abnormal Findings: [PECLSIG]	
Row 4	
Body System Examined: [PETEST]	Gastrointestinal
Not done: [PESTAT]	No
Examination Results: [PEORRES]	Normal
Abnormal Findings: [PECLSIG]	
Row 5	
Body System Examined: [PETEST]	Other
Not done: [PESTAT]	No
Examination Results: [PEORRES]	Abnormal CS
Abnormal Findings: [PECLSIG]	BILATERAL ARMS ECCHYMOSIS, LEFT HAND EDEMA
If Other, please specify: [PEOTHSP]	SKIN

AUDIT TRAIL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	29-Jun-2018 01:54 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [PEYN]		Yes
PE2DAT [PEDAT]		28-Jun-2018
PTIM1 [PTIM]		18:26
[Row 1] PETEST2 [PETEST]		General Appearance
[Row 1] PESTAT1 [PESTAT]		No
[Row 1] PEORRES1 [PEORRES]		Normal
[Row 2] PETEST2 [PETEST]		Respiratory
[Row 2] PESTAT1 [PESTAT]		No
[Row 2] PEORRES1 [PEORRES]		Normal
[Row 3] PETEST2 [PETEST]		Cardiovascular
[Row 3] PESTAT1 [PESTAT]		No
[Row 3] PEORRES1 [PEORRES]		Normal
[Row 4] PETEST2 [PETEST]		Gastrointestinal
[Row 4] PESTAT1 [PESTAT]		No
[Row 4] PEORRES1 [PEORRES]		Normal
[Row 5] PETEST2 [PETEST]		Other
[Row 5] PESTAT1		No

Variable	Old Value	New Value
[PESTAT]		
[Row 5] PEORRES1 [PEORRES]		Abnormal CS
[Row 5] PECLSIG1 [PECLSIG]		BILATERAL ARMS ECCHYMOSIS, LEFT HAND EDEMA
PEOTHSP1 [PEOTHSP]		SKIN

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	17-Jul-2018 02:26 PM PDT (UTC-07:00)	Form marked as Complete
System	29-Jun-2018 01:54 PM PDT (UTC-07:00)	Form marked as Not Complete
System	29-Jun-2018 01:54 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Day 6
FORM: Symptom Directed Physical Exam

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 5] PEORRES1	PER SOURCE, AE WAS RECORDED [29-Jun-2018 01:55 PM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [17-Jul-2018 02:26 PM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	29-Jun-2018 01:54 PM	17-Jul-2018 02:26 PM
	Description			
	New: Result is Abnormal CS, please confirm an AE has been recorded. **Old:** **By:** 29-Jun-2018 01:54 PM (b) (6) vinceandassociates.com ((b) (6) (b) (6)			

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]	09:00
Session End Time: [EXENTMB]	09:10
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 11:20 AM 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]		09:00
[Row 1] EXENTMB [EXENTMB]		09:10
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 11:20 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:35 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:15 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]	15:01
Session End Time: [EXENTMB]	15:04
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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	29-Jun-2018 09:25 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]		15:01
[Row 1] EXENTMB2 [EXENTMB]		15:04

Variable	Old Value	New Value
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 09:25 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:35 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:16 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	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 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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) algo pharm.com (b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: Day 6
FORM: Part B - Controlled 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 08:54 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:54 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]	18:09
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	63
PR Interval: [EGPR]	119
QRS Interval: [EGQRS]	89

QT Interval: [EGQT]	404
QTcB Interval: [EGQTCB]	414
QTcF: [EGQTCF]	411
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 01:52 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]		18:09
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		63
[Row 1] EG1PR [EGPR]		119
[Row 1] EG1QRS [EGQRS]		89
[Row 1] EG1QT [EGQT]		404
[Row 1] EGQTCB		414

Variable	Old Value	New Value
[EGQTCB]		
[Row 1] EG1QTCF [EGQTCF]		411
[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 01:52 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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 01:56 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 01:56 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:51 AM 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) 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 - 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	29-Jun-2018 01:56 PM 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 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 01:56 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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**
[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]	08-Aug-2018 11:51 AM 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) 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 - 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 01:56 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 01:56 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 01:56 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 01:56 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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
(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)	08-Aug-2018 11:51 AM 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 01:55 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 01:55 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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) 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 - PK Blood Sampling

Use: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	08:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:06
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	Yes
Time Unknown [PKACTNK]	
Comments: [PKCODE]	D - No Sample Collected due to difficult collection
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:13
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	A - Late due to difficult collection
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:33

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:01
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]	10:31
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]	11:03
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	11:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	A - Late due to difficult collection
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	12:00
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 01:46 PM 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]		08:55
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		28-Jun-2018
[Row 2] PKTIM		09:02

Variable	Old Value	New Value
[PKTIM]		
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		28-Jun-2018
[Row 3] PKTIM [PKTIM]		09:06
[Row 3] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		28-Jun-2018
[Row 4] PKTIM [PKTIM]		09:07
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKSTAT [PKSTAT]		Yes
[Row 5] PKCODE [PKCODE]		D - No Sample Collected due to difficult collection
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		28-Jun-2018
[Row 6] PKTIM [PKTIM]		09:13
[Row 6] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		28-Jun-2018
[Row 7] PKTIM [PKTIM]		09:15
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		28-Jun-2018
[Row 8] PKTIM [PKTIM]		09:20
[Row 9] PKTPT [PKTPT]		30 minute

Variable	Old Value	New Value
[Row 9] PKDAT [PKDAT]		28-Jun-2018
[Row 9] PKTIM [PKTIM]		09:33
[Row 9] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		28-Jun-2018
[Row 10] PKTIM [PKTIM]		09:45
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		28-Jun-2018
[Row 11] PKTIM [PKTIM]		10:01
[Row 11] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		28-Jun-2018
[Row 12] PKTIM [PKTIM]		10:31
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		28-Jun-2018
[Row 13] PKTIM [PKTIM]		11:03
[Row 13] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		28-Jun-2018
[Row 14] PKTIM [PKTIM]		11:35

Variable	Old Value	New Value
[Row 14] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		28-Jun-2018
[Row 15] PKTIM [PKTIM]		12:00

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 01:46 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: 1st Use - PK Blood Sampling

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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]	15:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:04

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:06
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:08
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:13
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:16
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:34
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:46

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:02
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]	16:31
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	17:01
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	17:31
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	18:01
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 01:51 PM 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]		15:00
[Row 1] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		28-Jun-2018
[Row 2] PKTIM1 [PKTIM]		15:04
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		28-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:06
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		28-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:08
[Row 5] PKTPT1 [PKTPT]		10 minute

Variable	Old Value	New Value
[Row 5] PKDAT1 [PKDAT]		28-Jun-2018
[Row 5] PKTIM1 [PKTIM]		15:11
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		28-Jun-2018
[Row 6] PKTIM1 [PKTIM]		15:13
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		28-Jun-2018
[Row 7] PKTIM1 [PKTIM]		15:16
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		28-Jun-2018
[Row 8] PKTIM1 [PKTIM]		15:21
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		28-Jun-2018
[Row 9] PKTIM1 [PKTIM]		15:34
[Row 9] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		28-Jun-2018
[Row 10] PKTIM1 [PKTIM]		15:46
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		28-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:02

Variable	Old Value	New Value
[Row 11] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		28-Jun-2018
[Row 12] PKTIM1 [PKTIM]		16:31
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		28-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:01
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		28-Jun-2018
[Row 14] PKTIM1 [PKTIM]		17:31
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		28-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:01

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: 2nd Use - PK Blood Sampling

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 01:51 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM 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 01:56 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 01:56 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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]	08-Aug-2018 11:51 AM 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: Day 6
FORM: Use Product Again - VAS 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 01:56 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 01:56 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Use Product Again - VAS 2nd use

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

CLINICAL DATA

VISIT: Early Term
FORM: Visit Date

Visit Done? [SVYN]	
Date of Visit: [SVSTDAT]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Visit Date

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

Visit: [LBVIS]	

Was the laboratory evaluation performed? [LBYN]	
Date of collection: [LBDAT]	
Time of Collection: [LBTIM]	
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Hematology Laboratory Evaluation

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

CLINICAL DATA

VISIT: Early Term
FORM: Urinalysis Laboratory Evaluation

Visit: [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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:54 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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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 01:41 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:54 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]	HAND SKIN DISCOLORATION - LEFT HAND
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]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	27-Jun-2018
Onset Time: [AESTTIM]	10:15
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	28-Jun-2018
End Time: [AEENTIM]	06:45
Time Unknown: [AEENTMNK]	
Row 2	
AE Identifier: [AESPID]	2
Adverse Event Term: [AETERM]	LEFT HAND SWELLING

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]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	27-Jun-2018
Onset Time: [AESTTIM]	12:00
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	30-Jun-2018
End Time: [AEENTIM]	
Time Unknown: [AEENTMNK]	Yes

Row 3	
AE Identifier: [AESPID]	3
Adverse Event Term: [AETERM]	PARESTHESIA RIGHT ARM, FACE
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]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	27-Jun-2018
Onset Time: [AESTTIM]	17:01
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	27-Jun-2018

End Time: [AEENTIM]	17:02
Time Unknown: [AEENTMNK]	
Row 4	
AE Identifier: [AESPID]	4
Adverse Event Term: [AETERM]	ECCHYMOSIS - BILATERAL ARMS AND HANDS
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]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	27-Jun-2018
Onset Time: [AESTTIM]	06:45
Time Unknown: [AESTTMNK]	

AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	05-Jul-2018
End Time: [AEENTIM]	
Time Unknown: [AEENTMNK]	Yes
Row 5	
AE Identifier: [AESPID]	5
Adverse Event Term: [AETERM]	VENIPUNCTURE SITE PAIN - BILATERAL ARMS
Is this an SAE? [AESER]	No
Severity: [AESEV]	MODERATE
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]	Yes
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	27-Jun-2018

Onset Time: [AESTTIM]	21:00
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	29-Jun-2018
End Time: [AEENTIM]	
Time Unknown: [AEENTMNK]	Yes

AUDIT TRAIL

VISIT: All Visits
FORM: Adverse Events

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	08-Aug-2018 03:23 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 5] AEOUT [AEOUT]	Unresolved/Ongoing	Resolved
[Row 5] AEONGO [AEONGO]	Yes	No
[Row 5] AEENDAT [AEENDAT]		29-Jun-2018
[Row 5] AEENTMNK [AEENTMNK]		Yes
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Aug-2018 01:25 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] AEENTMNK	No	Yes

Variable	Old Value	New Value
[AEENTMNK]		
[Row 4] AEENTMNK [AEENTMNK]	No	Yes
Logged in User	(b) (6) vinceandassociates.com ((b) (6)) (b) (6)	
Date/Time	06-Aug-2018 10:45 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 2] AEOUT [AEOUT]		Resolved
[Row 2] AEENDAT [AEENDAT]		30-Jun-2018
[Row 4] AEOUT [AEOUT]		Resolved
[Row 4] AEENDAT [AEENDAT]		05-Jul-2018
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 12:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 5] AEOUT [AEOUT]		Unresolved/Ongoing
[Row 5] AEONGO [AEONGO]	No	Yes
[Row 5] AEENTMNK [AEENTMNK]	No	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 12:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 5] AETERM [AETERM]	VENIPUNCTURE SITE PAIN	VENIPUNCTURE SITE PAIN - BILATERAL ARMS
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 02:17 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]		HAND SKIN DISCOLORATION - LEFT HAND
[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]		Unrelated
[Row 1] AETEAE [AETEAE]		No
[Row 1] AEOUT [AEOUT]		Resolved
[Row 1] AESTDAT [AESTDAT]		27-Jun-2018
[Row 1] AESTTIM [AESTTIM]		10:15
[Row 1] AEONGO [AEONGO]		No
[Row 1] AEENDAT [AEENDAT]		28-Jun-2018
[Row 1] AEENTIM [AEENTIM]		06:45
[Row 2] AESPID [AESPID]		2
[Row 2] AETERM [AETERM]		LEFT HAND SWELLING
[Row 2] AESER [AESER]		No

Variable	Old Value	New Value
[Row 2] AESEV [AESEV]		MILD
[Row 2] AEFREQ [AEFREQ]		Continuous
[Row 2] AEACN [AEACN]		No Action Taken
[Row 2] AECONTRT [AECONTRT]		No
[Row 2] AEDIS [AEDIS]		No
[Row 2] AEREL [AEREL]		Unrelated
[Row 2] AETEAE [AETEAE]		No
[Row 2] AESTDAT [AESTDAT]		27-Jun-2018
[Row 2] AESTTIM [AESTTIM]		12:00
[Row 2] AEONGO [AEONGO]		No
[Row 2] AEENTMNK [AEENTMNK]		No
[Row 3] AESPID [AESPID]		3
[Row 3] AETERM [AETERM]		PARESTHESIA RIGHT ARM, FACE
[Row 3] AESER [AESER]		No
[Row 3] AESEV [AESEV]		MILD
[Row 3] AEFREQ [AEFREQ]		Single Episode
[Row 3] AEACN [AEACN]		No Action Taken
[Row 3] AECONTRT [AECONTRT]		No
[Row 3] AEDIS [AEDIS]		No
[Row 3] AEREL [AEREL]		Unrelated
[Row 3] AETEAE [AETEAE]		No

Variable	Old Value	New Value
[Row 3] AEOUT [AEOUT]		Resolved
[Row 3] AESTDAT [AESTDAT]		27-Jun-2018
[Row 3] AESTTIM [AESTTIM]		17:01
[Row 3] AEONGO [AEONGO]		No
[Row 3] AEENDAT [AEENDAT]		27-Jun-2018
[Row 3] AEENTIM [AEENTIM]		17:02
[Row 4] AESPID [AESPID]		4
[Row 4] AETERM [AETERM]		ECCHYMOSIS - BILATERAL ARMS AND HANDS
[Row 4] AESER [AESER]		No
[Row 4] AESEV [AESEV]		MILD
[Row 4] AEFREQ [AEFREQ]		Continuous
[Row 4] AEACN [AEACN]		No Action Taken
[Row 4] AECONTRT [AECONTRT]		No
[Row 4] AEDIS [AEDIS]		No
[Row 4] AEREL [AEREL]		Unrelated
[Row 4] AETEAE [AETEAE]		No
[Row 4] AESTDAT [AESTDAT]		27-Jun-2018
[Row 4] AESTTIM [AESTTIM]		06:45
[Row 4] AEONGO [AEONGO]		No
[Row 4] AEENTMNK [AEENTMNK]		No
[Row 5] AECMNM_deleted [AECMNM_deleted]		2

Variable	Old Value	New Value
[Row 5] AESPID [AESPID]		5
[Row 5] AETERM [AETERM]		VENIPUNCTURE SITE PAIN
[Row 5] AESER [AESER]		No
[Row 5] AESEV [AESEV]		MODERATE
[Row 5] AEFREQ [AEFREQ]		Intermittent
[Row 5] AEACN [AEACN]		No Action Taken
[Row 5] AECONTRT [AECONTRT]		Yes
[Row 5] AEDIS [AEDIS]		No
[Row 5] AEREL [AEREL]		Unrelated
[Row 5] AETEAE [AETEAE]		No
[Row 5] AESTDAT [AESTDAT]		27-Jun-2018
[Row 5] AESTTIM [AESTTIM]		21:00
[Row 5] AEONGO [AEONGO]		No
[Row 5] AEENTMNK [AEENTMNK]		No

FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Adverse Events

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	19-Sep-2018 02:31 PM PDT (UTC-07:00)	Form marked as Complete
System	29-Jun-2018 02:17 PM PDT (UTC-07:00)	Form marked as Not Complete
System	29-Jun-2018 02:17 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:54 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)	19-Sep-2018 02:31 PM PDT (UTC-07:00)	Form marked as "Form Monitored".
(b) (6) vinceandassociates.com ((b) (6)	08-Aug-2018 03:22 PM PDT (UTC-07:00)	Updated information (Form partially unmarked as "Form Monitored").(AEOUT [5], AEONGO [5], AEENDAT [5], AEENTIM [5], AEENTMNK [5])
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 11:50 AM PDT (UTC-07:00)	Form partially marked as "Form Monitored". (AEYN, AESPID [1], AETERM [1], AESER [1], AESEV [1], AEFREQ [1], AEACN [1], AECONTRT [1], AEDIS [1], AEREL [1], AETEAE [1], AEOUT [1], AESTDAT [1], AESTTIM [1], AESTTMNK [1], AEONGO [1], AEENDAT [1], AEENTIM [1], AEENTMNK [1], AESPID [2], AETERM [2], AESER [2], AESEV [2], AEFREQ [2], AEACN [2], AECONTRT [2], AEDIS [2], AEREL [2], AETEAE [2], AEOUT [2], AESTDAT [2], AESTTIM [2], AESTTMNK [2], AEONGO [2], AEENDAT [2], AEENTIM [2], AEENTMNK [2], AESPID [3], AETERM [3], AESER [3], AESEV [3], AEFREQ [3], AEACN [3], AECONTRT [3], AEDIS [3], AEREL [3], AETEAE [3], AEOUT [3], AESTDAT [3], AESTTIM [3], AESTTMNK [3], AEONGO [3], AEENDAT [3], AEENTIM [3], AEENTMNK [3], AESPID [4], AETERM [4], AESER [4], AESEV [4], AEFREQ [4], AEACN [4], AECONTRT [4], AEDIS [4], AEREL [4], AETEAE [4], AEOUT [4], AESTDAT [4], AESTTIM [4], AESTTMNK [4], AEONGO [4], AEENDAT [4], AEENTIM [4], AEENTMNK [4], AESPID [5], AETERM [5], AESER [5], AESEV [5], AEFREQ [5], AEACN [5], AECONTRT [5], AEDIS [5], AEREL [5], AETEAE [5], AESTDAT [5], AESTTIM [5], AESTTMNK [5], AEONGO [5], AEENDAT [5], AEENTIM [5], AEENTMNK [5])

QUERIES

VISIT: All Visits
FORM: Adverse Events

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 5] AEOUT	DATA HAS BEEN UPDATED [08-Aug-2018 03:23 PM by (b) (6) vinceandassociates.com (b) (6) Response satisfies query [19-Sep-2018 02:31 PM by (b) (6) gmai	08-Aug-2018 11:50 AM	19-Sep-2018 02:31 PM

ID	Variable	Responses/Reasons	Opened	Closed
		l.com ([redacted] [redacted]		
	Description			
	New: per source this resolved on 29JUN2018 - time UNK. please correct else clarify. **Old:** **By:** 08-Aug-2018 11:50 AM [redacted] gmail.com ([redacted] [redacted]			
	[Row 5] AEENDAT	AE IS ONGOING, END DATE NOT APPLICABLE [03-Jul-2018 09:09 AM by [redacted] vinceandassociates.com ([redacted] Data Updated [08-Aug-2018 03:23 PM]	29-Jun-2018 02:17 PM	08-Aug-2018 03:23 PM
	Description			
	New: End Date is missing. However, Outcome is Resolved, Resolved with Sequelae, Fatal. Please clarify. **Old:** **By:** 29-Jun-2018 02:17 PM System			
	[Row 4] AEENDAT	Data Updated [06-Aug-2018 10:45 AM]	29-Jun-2018 02:17 PM	06-Aug-2018 10:45 AM
	Description			
	New: End Date is missing. However, Outcome is Resolved, Resolved with Sequelae, Fatal. Please clarify. **Old:** **By:** 29-Jun-2018 02:17 PM System			
	[Row 2] AEENDAT	Data Updated [06-Aug-2018 10:45 AM]	29-Jun-2018 02:17 PM	06-Aug-2018 10:45 AM
	Description			
	New: End Date is missing. However, Outcome is Resolved, Resolved with Sequelae, Fatal. Please clarify. **Old:** **By:** 29-Jun-2018 02:17 PM System			
	[Row 5] AEENTIM	Data Updated [02-Jul-2018 12:03 PM by [redacted] vinceandass	29-Jun-2018 02:17 PM	02-Jul-2018 12:03 PM

ID	Variable	Responses/Reasons	Opened	Closed
		ociates.com ([redacted]		
	Description			
	New: Time is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM [redacted] vinceandassociates.com ([redacted]			
	[Row 4] AEENTIM	time unk [06-Aug-2018 10:45 AM by [redacted] vinceandassociates.com ([redacted] Data Updated [07-Aug-2018 01:25 PM by [redacted] vinceandassociates.com ([redacted]	29-Jun-2018 02:17 PM	07-Aug-2018 01:25 PM
	Description			
	New: Time is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM [redacted] vinceandassociates.com ([redacted]			
	[Row 2] AEENTIM	time unk [06-Aug-2018 10:45 AM by [redacted] vinceandassociates.com ([redacted] Data Updated [07-Aug-2018 01:25 PM by [redacted] vinceandassociates.com ([redacted]	29-Jun-2018 02:17 PM	07-Aug-2018 01:25 PM
	Description			
	New: Time is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM [redacted] vinceandassociates.com ([redacted]			
	[Row 5] AEOUT	Data Updated [02-Jul-2018 12:03 PM	29-Jun-2018 02:17 PM	02-Jul-2018 12:03 PM

ID	Variable	Responses/Reasons	Opened	Closed
		by (b) (6) vinceandassociates.com ((b) (6)		
	Description			
	New: Outcome is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 4] AEOUT	Data Updated [06-Aug-2018 10:45 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	29-Jun-2018 02:17 PM	06-Aug-2018 10:45 AM
	Description			
	New: Outcome is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 2] AEOUT	Data Updated [06-Aug-2018 10:45 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	29-Jun-2018 02:17 PM	06-Aug-2018 10:45 AM
	Description			
	New: Outcome is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 5] AEENDAT	Data Updated [02-Jul-2018 12:03 PM by (b) (6) vinceandassociates.com ((b) (6)	29-Jun-2018 02:17 PM	02-Jul-2018 12:03 PM
	Description			
	New: Date is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 4] AEENDAT	Data Updated [06-Aug-2018 10:45	29-Jun-2018 02:17 PM	06-Aug-2018 10:45 AM

ID	Variable	Responses/Reasons	Opened	Closed
		AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)		
	Description			
	New: Date is missing, please review **Old:** **By:** 29-Jun-2018 02:17 PM (b) (6) vinceandassociates.com (b) (6)			
	[Row 2] AEENDAT	Data Updated [06-Aug-2018 10:45 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	29-Jun-2018 02:17 PM	06-Aug-2018 10:45 AM
	Description			
	New: Date is missing, please review **Old:** **By:** 29-Jun-2018 02:17 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]	Yes

Row 1	
CM Number: [CMNUM]	1
Medication/Therapy/Procedure: [CMTRT]	IBUPROFEN
Indication: [CMINDC]	Medical History
If Other, please specify: [CMINDOT]	
Adverse Event #: [CMAENUM]	
Medical History #: [CMMHNUM]	1
Strength: [CMDOSE]	UNKNOWN
Unit: [CMDOSU]	Unknown
If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	2
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	UNKNOWN
Unit: [CMTOTUN]	Unknown
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	

Frequency: [CMDOSFRQ]	ONCE
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	17-Jun-2018
Start Time: [CMSTTIM]	15:00
Time Unknown [CMSTTNK]	
End Date: [CMENDAT]	17-Jun-2018
End Time: [CMENTIM]	15:00
Time Unknown [CMENTNK]	
Ongoing? [CMONGO]	
Row 2	
CM Number: [CMNUM]	2
Medication/Therapy/Procedure: [CMTRT]	IBUPROFEN
Indication: [CMINDC]	Adverse Event
If Other, please specify: [CMINDOT]	
Adverse Event #: [CMAENUM]	5
Medical History #: [CMMHNUM]	
Strength: [CMDOSE]	200
Unit: [CMDOSU]	mg

If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	2
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	400
Unit: [CMTOTUN]	mg
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	ONCE
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	28-Jun-2018
Start Time: [CMSTTIM]	06:59
Time Unknown [CMSTTNK]	
End Date: [CMENDAT]	28-Jun-2018
End Time: [CMENTIM]	06:59
Time Unknown [CMENTNK]	

Ongoing? [CMONGO]	

AUDIT TRAIL

VISIT: All Visits
FORM: Concomitant Medications

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 11:59 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 1] CMENDAT [CMENDAT]		17-Jun-2018
[Row 1] CMENTIM [CMENTIM]		15:00
[Row 1] CMENTNK [CMENTNK]	No	
[Row 1] CMONGO [CMONGO]	No	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 01:59 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] CMNUM [CMNUM]		2
[Row 2] CMTRT [CMTRT]		IBUPROFEN
[Row 2] CMINDC [CMINDC]		Adverse Event
[Row 2] CMAENUM [CMAENUM]		5
[Row 2] CMDOSE [CMDOSE]		200
[Row 2] CMDOSU [CMDOSU]		mg
[Row 2] CMQUANT		2

Variable	Old Value	New Value
[CMQUANT]		
[Row 2] CMDOSFRM [CMDOSFRM]		TABLET
[Row 2] CMTOTDOS [CMTOTDOS]		400
[Row 2] CMTOTUN [CMTOTUN]		mg
[Row 2] CMROUTE [CMROUTE]		ORAL
[Row 2] CMDOSFRQ [CMDOSFRQ]		ONCE
[Row 2] CMSTDAT [CMSTDAT]		28-Jun-2018
[Row 2] CMSTTIM [CMSTTIM]		06:59
[Row 2] CMENDAT [CMENDAT]		28-Jun-2018
[Row 2] CMENTIM [CMENTIM]		06:59
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 01:55 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	

Variable	Old Value	New Value
[Row 1] CMINDC [CMINDC]		Medical History
[Row 1] CMMHNUM [CMMHNUM]		1
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 01:55 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	

Variable	Old Value	New Value
CMYN [CMYN]		Yes
[Row 1] CMNUM [CMNUM]		1
[Row 1] CMTRT [CMTRT]		IBUPROFEN
[Row 1] CMDOSE		UNKNOWN

Variable	Old Value	New Value
[CMDOSE]		
[Row 1] CMDOSU [CMDOSU]		Unknown
[Row 1] CMQUANT [CMQUANT]		2
[Row 1] CMDOSFRM [CMDOSFRM]		TABLET
[Row 1] CMTOTDOS [CMTOTDOS]		UNKNOWN
[Row 1] CMTOTUN [CMTOTUN]		Unknown
[Row 1] CMROUTE [CMROUTE]		ORAL
[Row 1] CMDOSFRQ [CMDOSFRQ]		ONCE
[Row 1] CMSTDAT [CMSTDAT]		17-Jun-2018
[Row 1] CMSTTIM [CMSTTIM]		15:00
[Row 1] CMENTNK [CMENTNK]		No
[Row 1] CMONGO [CMONGO]		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	02-Jul-2018 11:59 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 01:55 PM PDT (UTC-07:00)	Form marked as Not Complete
System	27-Jun-2018 01:55 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 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)	08-Aug-2018 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: All Visits
FORM: Concomitant Medications

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] CMMHNUM	Data Updated [27-Jun-2018 01:55 PM by (b) (6) vinceandassociates.com (b) (6)	27-Jun-2018 01:55 PM	27-Jun-2018 01:55 PM
	Description			
	New: Medical History # is missing, please review **Old:** **By:** 27-Jun-2018 01:55 PM (b) (6) vinceandassociates.com (b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] CMINDC	Data Updated [27-Jun-2018 01:55 PM by (b) (6) vinceandassociates.com ((b) (6)	27-Jun-2018 01:55 PM	27-Jun-2018 01:55 PM
	Description			
	New: Indication is missing, please review **Old:** **By:** 27-Jun-2018 01:55 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] CMENTIM	Data Updated [02-Jul-2018 11:59 AM by (b) (6) vinceandassociates.com ((b) (6)	27-Jun-2018 01:55 PM	02-Jul-2018 11:59 AM
	Description			
	New: End Time is missing, please review **Old:** **By:** 27-Jun-2018 01:55 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] CMENDAT	Data Updated [02-Jul-2018 11:59 AM by (b) (6) vinceandassociates.com ((b) (6)	27-Jun-2018 01:55 PM	02-Jul-2018 11:59 AM
	Description			
	New: End Date is missing, please review **Old:** **By:** 27-Jun-2018 01:55 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] CMAENUM	Data Updated [27-Jun-2018 01:55 PM by (b) (6) vinceandassociates.com ((b) (6)	27-Jun-2018 01:55 PM	27-Jun-2018 01:55 PM
	Description			
	New: Adverse Event # is missing, please review **Old:** **By:** 27-Jun-2018 01:55 PM (b) (6) vinceandassociates.com ((b) (6)			

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

CLINICAL DATA

VISIT: Unscheduled Visit
FORM: Unscheduled Vital Signs (25-Jun-2018)

Visit: [VSVIS]	Day -1
Were vital signs measured? [VSPERF]	Yes
Time Seated: [VS1TIMS]	08:03
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	22-Jun-2018
Time Taken: [VSTIM]	08:08
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	Yes
Result: [VSORRES]	
Unit: [VSORRESU]	C

MD Safety Review: [VSCLSIG]	
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	149
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	93
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	84
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

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

AUDIT TRAIL

VISIT: Unscheduled Visit
FORM: Unscheduled Vital Signs (25-Jun-2018)

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 12:23 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSVIS_1 [VSVIS]		Day -1
VSPERF_1 [VSPERF]		Yes
VSTIMS_1 [VS1TIMS]		08:03
VS1DAT_1 [VSDAT]		22-Jun-2018
VSTIM_1 [VSTIM]		08:08
[Row 1] VSTEST_1 [VSTEST]		Oral Temperature
[Row 1] VSSTAT_1 [VSSTAT]		Yes
[Row 1] VSORRESU_1 [VSORRESU]		C
[Row 2] VSTEST_1		Systolic Blood Pressure

Variable	Old Value	New Value
[VSTEST]		
[Row 2] VSORRES_1 [VSORRES]		149
[Row 2] VSORRESU_1 [VSORRESU]		mmHg
[Row 2] VSCLSIG_1 [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST_1 [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES_1 [VSORRES]		93
[Row 3] VSORRESU_1 [VSORRESU]		mmHg
[Row 3] VSCLSIG_1 [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST_1 [VSTEST]		Pulse Rate
[Row 4] VSORRES_1 [VSORRES]		84
[Row 4] VSORRESU_1 [VSORRESU]		beats/min
[Row 4] VSCLSIG_1 [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST_1 [VSTEST]		Respirations
[Row 5] VSSTAT_1 [VSSTAT]		Yes
[Row 5] VSORRESU_1 [VSORRESU]		breaths/min

FORM STATUS CHANGE LOG

VISIT: Unscheduled Visit
FORM: Unscheduled Vital Signs (25-Jun-2018)

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 12:23 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:54 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Unscheduled Visit
FORM: Unscheduled Vital Signs (25-Jun-2018)

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)	08-Aug-2018 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Unscheduled Visit
FORM: Unscheduled Vital Signs (25-Jun-2018)

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