Table of Contents

01-086 16

By Visit

- Screening 19
  - Visit Date 19
    - Data 19
    - Audit Trail 19
  - ICF 20
    - Data 20
    - Audit Trail 21
  - INCL/EXCL Criteria Summary 22
    - Data 22
    - Audit Trail 22
  - Demographics 23
    - Data 23
    - Audit Trail 24
  - Medical History 26
    - Data 26
    - Audit Trail 29
    - Query Log 32
  - Complete Physical Examination 33
    - Data 33
    - Audit Trail 36
  - Height, Weight and BMI 38
    - Data 38
    - Audit Trail 39
  - Serology Lab Evaluation 40
    - Data 40
    - Audit Trail 41
  - Serum Pregnancy Test 43
    - Data 43
    - Audit Trail 43
  - Vital Signs 44
    - Data 44
    - Audit Trail 47
  - UDS and Alcohol Laboratory Evaluation 49
    - Data 49
    - Audit Trail 50
  - Cotinine Evaluation 51
    - Data 51
    - Audit Trail 52
  - Chemistry Laboratory Evaluation 53
    - Data 53
    - Audit Trail 54

Table of Contents

Hematology Laboratory Evaluation 56
Data 56
Audit Trail 57
Urinalysis Laboratory Evaluation 58
Data 58
Audit Trail 59
Endocrinology Evaluation 60
Data 60
Audit Trail 61
ECG Test Results 62
Data 62
Audit Trail 63
Female Contraceptive Method 65
Data 65
Audit Trail 66
Tobacco Use 68
Data 68
Audit Trail 71
Query Log 73
Day -1 77
Visit Date 77
Data 77
Audit Trail 77
Urine Pregnancy Test 78
Data 78
Audit Trail 79
Vital Signs 80
Data 80
Audit Trail 82
UDS and Alcohol Laboratory Evaluation 85
Data 85
Audit Trail 86
Symptom Directed Physical Exam 87
Data 87
Audit Trail 88
Day 1 89
Visit Date 89
Data 89
Audit Trail 89
Part A - Usual Brand Dose Log 91
Data 91
Part A - VLN Dosing Log 92
Data 92

Audit Trail 94
Part A - Nicorette Dosing Log 97
Data 97
Randomization 98
Data 98
Audit Trail 99
Use Product Again - VAS 100
Data 100
Audit Trail 101
Day 2 102
Visit Date 102
Data 102
Audit Trail 102
Part A - Usual Brand Dose Log 103
Data 103
Audit Trail 106
Query Log 118
Part A - VLN Dosing Log 120
Data 120
Part A - Nicorette Dosing Log 121
Data 121
Use Product Again - VAS 122
Data 122
Audit Trail 122
Day 3 123
Visit Date 123
Data 123
Audit Trail 124
Part A - Usual Brand Dose Log 125
Data 125
Part A - VLN Dosing Log 126
Data 126
Part A - Nicorette Dosing Log 127
Data 127
Audit Trail 128
Use Product Again - VAS 130
Data 130
Audit Trail 131
Day 4 132
Visit Date 132
Data 132
Audit Trail 132
Randomization 133

Data 133
Audit Trail 133
Part B - Controlled Nicorette Dosing Log-1 135
Data 135
Part B - Uncontrolled Nicorette Dosing Log 136
Data 136
Part B - Uncontrolled Usual Brand Dosing Log 137
Data 137
Audit Trail 143
Query Log 146
Part B - Controlled Usual Brand Dosing Log 147
Data 147
Audit Trail 150
Part B - Controlled VLN Dosing Log 154
Data 154
Part B - Uncontrolled VLN Dosing Log 155
Data 155
1st Use - Tobacco/Nicotine Questionnaire 156
Data 156
Audit Trail 157
2nd Use - Tobacco/Nicotine Questionnaire 158
Data 158
Audit Trail 159
1st Use - Direct Effects of Product Questionnaire 160
Data 160
Audit Trail 160
2nd Use - Direct Effects of Product Questionnaire 161
Data 161
Audit Trail 162
Query Log 163
1st Use - PK Blood Sampling 164
Data 164
Audit Trail 170
2nd Use - PK Blood Sampling 173
Data 173
Audit Trail 179
Use Product Again - VAS 1st use 183
Data 183
Audit Trail 183
Use Product Again - VAS 2nd use 184
Data 184
Audit Trail 185
Day 5 186

Table of Contents

Visit Date 186
Data 186
Audit Trail 186
Part B - Controlled Nicorette Dosing Log 187
Data 187
Audit Trail 188
Part B - Uncontrolled Nicorette Dosing Log 189
Data 189
Audit Trail 190
Part B - Uncontrolled Usual Brand Dosing Log 191
Data 191
Part B - Controlled Usual Brand Dosing Log 193
Data 193
Part B - Controlled VLN Dosing Log 194
Data 194
Part B - Uncontrolled VLN Dosing Log 195
Data 195
1st Use - Tobacco/Nicotine Questionnaire 197
Data 197
Audit Trail 197
2nd Use - Tobacco/Nicotine Questionnaire 198
Data 198
Audit Trail 199
1st Use - Direct Effects of Product Questionnaire 200
Data 200
Audit Trail 200
2nd Use - Direct Effects of Product Questionnaire 202
Data 202
Audit Trail 202
1st Use - PK Blood Sampling 203
Data 203
Audit Trail 209
2nd Use - PK Blood Sampling 213
Data 213
Audit Trail 218
Use Product Again - VAS 1st use 222
Data 222
Audit Trail 222
Use Product Again - VAS 2nd use 223
Data 223
Audit Trail 224
Day 6 225
Visit Date 225

Data 225
Audit Trail 225
Vital Signs 226
Data 226
Audit Trail 229
Chemistry Laboratory Evaluation 231
Data 231
Audit Trail 232
Hematology Laboratory Evaluation 233
Data 233
Audit Trail 234
Query Log 236
Urinalysis Laboratory Evaluation 236
Data 236
Audit Trail 237
Symptom Directed Physical Exam 238
Data 238
Audit Trail 239
Part B - Controlled Nicorette Dosing Log-1 240
Data 240
Part B - Uncontrolled Nicorette Dosing Log 241
Data 241
Part B - Controlled Usual Brand Dosing Log 242
Data 242
Part B - Uncontrolled Usual Brand Dosing Log 244
Data 244
Part B - Controlled VLN Dosing Log 245
Data 245
Audit Trail 249
Part B - Uncontrolled VLN Dosing Log 252
Data 252
Audit Trail 257
ECG Test Results 260
Data 260
Audit Trail 261
Query Log 262
1st Use - Tobacco/Nicotine Questionnaire 263
Data 263
Audit Trail 264
2nd Use - Tobacco/Nicotine Questionnaire 265
Data 265
Audit Trail 265
1st Use - Direct Effects of Product Questionnaire 266

Data 266
Audit Trail 267
2nd Use - Direct Effects of Product Questionnaire 268
Data 268
Audit Trail 269
End of Study 270
Data 270
Audit Trail 270
1st Use - PK Blood Sampling 272
Data 272
Audit Trail 278
2nd Use - PK Blood Sampling 281
Data 281
Audit Trail 287
Use Product Again - VAS 1st use 291
Data 291
Audit Trail 292
Use Product Again - VAS 2nd use 293
Data 293
Audit Trail 293
Early Term 294
Visit Date 294
Data 294
Vital Signs 295
Data 295
Chemistry Laboratory Evaluation 296
Data 296
Hematology Laboratory Evaluation 298
Data 298
Urinalysis Laboratory Evaluation 299
Data 299
Symptom Directed Physical Exam 300
Data 300
ECG Test Results 301
Data 301
End of Study 303
Data 303
1st Use - PK Blood Sampling 304
Data 304
2nd Use - PK Blood Sampling 305
Data 305
All Visits 306
Adverse Events 306

Data 306
Audit Trail 307
Concomitant Medications 309
Data 309
Audit Trail 311
By Domain
Visit Date 19
Screening 19
Data 19
Audit Trail 19
Day -1 77
Data 77
Audit Trail 77
Day 1 89
Data 89
Audit Trail 89
Day 2 102
Data 102
Audit Trail 102
Day 3 123
Data 123
Audit Trail 124
Day 4 132
Data 132
Audit Trail 132
Day 5 186
Data 186
Audit Trail 186
Day 6 225
Data 225
Audit Trail 225
Early Term 294
Data 294
ICF 20
Screening 19
Data 20
Audit Trail 21
INCL/EXCL Criteria Summary 22
Screening 19
Data 22
Audit Trail 22
Demographics 23
Screening 19

Data 23
Audit Trail 24
Medical History 26
Screening 19
Data 26
Audit Trail 29
Query Log 32
Complete Physical Examination 33
Screening 19
Data 33
Audit Trail 36
Height, Weight and BMI 38
Screening 19
Data 38
Audit Trail 39
Serology Lab Evaluation 40
Screening 19
Data 40
Audit Trail 41
Serum Pregnancy Test 43
Screening 19
Data 43
Audit Trail 43
Vital Signs 44
Screening 19
Data 44
Audit Trail 47
Day -1 77
Data 80
Audit Trail 82
Day 6 225
Data 226
Audit Trail 229
Early Term 294
Data 295
UDS and Alcohol Laboratory Evaluation 49
Screening 19
Data 49
Audit Trail 50
Day -1 77
Data 85
Audit Trail 86
Cotinine Evaluation 51

Screening 19
Data 51
Audit Trail 52
Chemistry Laboratory Evaluation 53
Screening 19
Data 53
Audit Trail 54
Day 6 225
Data 231
Audit Trail 232
Early Term 294
Data 296
Hematology Laboratory Evaluation 56
Screening 19
Data 56
Audit Trail 57
Day 6 225
Data 233
Audit Trail 234
Query Log 236
Early Term 294
Data 298
Urinalysis Laboratory Evaluation 58
Screening 19
Data 58
Audit Trail 59
Day 6 225
Data 236
Audit Trail 237
Early Term 294
Data 299
Endocrinology Evaluation 60
Screening 19
Data 60
Audit Trail 61
ECG Test Results 62
Screening 19
Data 62
Audit Trail 63
Day 6 225
Data 260
Audit Trail 261
Query Log 262

Early Term 294
Data 301
Female Contraceptive Method 65
Screening 19
Data 65
Audit Trail 66
Tobacco Use 68
Screening 19
Data 68
Audit Trail 71
Query Log 73
Urine Pregnancy Test 78
Day -1 77
Data 78
Audit Trail 79
Symptom Directed Physical Exam 87
Day -1 77
Data 87
Audit Trail 88
Day 6 225
Data 238
Audit Trail 239
Early Term 294
Data 300
Part A - Usual Brand Dose Log 91
Day 1 89
Data 91
Day 2 102
Data 103
Audit Trail 106
Query Log 118
Day 3 123
Data 125
Part A - VLN Dosing Log 92
Day 1 89
Data 92
Audit Trail 94
Day 2 102
Data 120
Day 3 123
Data 126
Part A - Nicorette Dosing Log 97
Day 1 89

Data 97
Day 2 102
Data 121
Day 3 123
Data 127
Audit Trail 128
Randomization 98
Day 1 89
Data 98
Audit Trail 99
Day 4 132
Data 133
Audit Trail 133
Use Product Again - VAS 100
Day 1 89
Data 100
Audit Trail 101
Day 2 102
Data 122
Audit Trail 122
Day 3 123
Data 130
Audit Trail 131
Part B - Controlled Nicorette Dosing Log-1 135
Day 4 132
Data 135
Day 6 225
Data 240
Part B - Uncontrolled Nicorette Dosing Log 136
Day 4 132
Data 136
Day 5 186
Data 189
Audit Trail 190
Day 6 225
Data 241
Part B - Uncontrolled Usual Brand Dosing Log 137
Day 4 132
Data 137
Audit Trail 143
Query Log 146
Day 5 186
Data 191

Day 6 225
Data 244
Part B - Controlled Usual Brand Dosing Log 147
Day 4 132
Data 147
Audit Trail 150
Day 5 186
Data 193
Day 6 225
Data 242
Part B - Controlled VLN Dosing Log 154
Day 4 132
Data 154
Day 5 186
Data 194
Day 6 225
Data 245
Audit Trail 249
Part B - Uncontrolled VLN Dosing Log 155
Day 4 132
Data 155
Day 5 186
Data 195
Day 6 225
Data 252
Audit Trail 257
1st Use - Tobacco/Nicotine Questionnaire 156
Day 4 132
Data 156
Audit Trail 157
Day 5 186
Data 197
Audit Trail 197
Day 6 225
Data 263
Audit Trail 264
2nd Use - Tobacco/Nicotine Questionnaire 158
Day 4 132
Data 158
Audit Trail 159
Day 5 186
Data 198
Audit Trail 199

Day 6 225
Data 265
Audit Trail 265
1st Use - Direct Effects of Product Questionnaire 160
Day 4 132
Data 160
Audit Trail 160
Day 5 186
Data 200
Audit Trail 200
Day 6 225
Data 266
Audit Trail 267
2nd Use - Direct Effects of Product Questionnaire 161
Day 4 132
Data 161
Audit Trail 162
Query Log 163
Day 5 186
Data 202
Audit Trail 202
Day 6 225
Data 268
Audit Trail 269
1st Use - PK Blood Sampling 164
Day 4 132
Data 164
Audit Trail 170
Day 5 186
Data 203
Audit Trail 209
Day 6 225
Data 272
Audit Trail 278
Early Term 294
Data 304
2nd Use - PK Blood Sampling 173
Day 4 132
Data 173
Audit Trail 179
Day 5 186
Data 213
Audit Trail 218

Day 6 225
Data 281
Audit Trail 287
Early Term 294
Data 305
Use Product Again - VAS 1st use 183
Day 4 132
Data 183
Audit Trail 183
Day 5 186
Data 222
Audit Trail 222
Day 6 225
Data 291
Audit Trail 292
Use Product Again - VAS 2nd use 184
Day 4 132
Data 184
Audit Trail 185
Day 5 186
Data 223
Audit Trail 224
Day 6 225
Data 293
Audit Trail 293
Part B - Controlled Nicorette Dosing Log 187
Day 5 186
Data 187
Audit Trail 188
End of Study 270
Day 6 225
Data 270
Audit Trail 270
Early Term 294
Data 303
Adverse Events 306
All Visits 306
Data 306
Audit Trail 307
Concomitant Medications 309
All Visits 306
Data 309
Audit Trail 311

Site:	Site A
Group:	Group A
Medrio ID:	0027
Subject Identifier:	01-086
Status:	Completed
Timezone:	Pacific Standard Time
Study Name:	CEG-P9-153

SUBJECT INFORMATION HISTORY

Object	Date Time	User	Old Value	New Value
Subject Status	13-Jun-2018 09:23 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)	Enrolled	Completed
Subject ID	31-May-2018 09:38 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		01-086
Medrio ID	31-May-2018 09:38 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		27
Subject Status	31-May-2018 09:38 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Enrolled
Site	31-May-2018 09:38 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Site A
Group	31-May-2018 09:38 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Group A
ePRO Enabled	31-May-2018 09:38 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		No

SUBJECT LOCKING HISTORY

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

VISIT LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Screening
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	21-May-2018

AUDIT TRAIL

VISIT: Screening
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 09:39 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		21-May-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	31-May-2018 09:39 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:40 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Visit Date

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

CLINICAL DATA

VISIT: Screening
FORM: ICF

Was the most current IRB approved version of the Informed Consent signed by the subject? [DSYN]	Yes
Row 1	
Date Subject Signed ICF: (Original signature) [DSDAT]	21-May-2018
ICF Version: [DSVERS]	v3 ICF CEG-P9-153
ICF Version Date: [DSVDAT]	01-May-2018

AUDIT TRAIL

VISIT: Screening
FORM: ICF

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	31-May-2018 09:40 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DSYN [DSYN]		Yes
[Row 1] DSDATE [DSDAT]		21-May-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	31-May-2018 09:40 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ICF

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]	30-Jul-2018 02:40 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: ICF

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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)	
Date/Time	31-May-2018 09:50 AM PDT (UTC-07:00)	
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	31-May-2018 09:50 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 01:47 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algopharm.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]	21-May-2018

Date of Birth: [DMBRTHDAT]	(b) (6)
Age: [DMAGE]	50
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)	
Date/Time	31-May-2018 10:38 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
DMBRTHDAT [DMBRTHDAT]	31-Dec-1978	(b) (6)
DMAGE [DMAGE]	39	50
DMSEX [DMSEX]	M	F
DMRACE [DMRACE]	BLACK OR AFRICAN AMERICAN	WHITE
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 09:52 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DMDAT [DMDAT]		21-May-2018
DMBRTHDAT [DMBRTHDAT]		31-Dec-1978
DMAGE [DMAGE]		39

Variable	Old Value	New Value
DMAGEU [DMAGEU]		YEARS
DMSEX [DMSEX]		M
DMETHNIC [DMETHNIC]		NOT HISPANIC OR LATINO
DMRACE [DMRACE]		BLACK OR AFRICAN AMERICAN

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	31-May-2018 09:52 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:39 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Demographics

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

CLINICAL DATA

VISIT: Screening
FORM: Medical History

Does the subject have any relevant medical or surgical history (including drug allergies)? [MHYN]	Yes
Date of Visit: [MHDAT]	21-May-2018
Row 1	
Medical History #: [MHNUM]	1
Body System Code: [MHSCAT]	Immunologic/Allergies
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	ALLERGY PCN- HIVES
Onset Date: [MHSTDAT]	UN-UNK-1974
Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	Yes
Safety Review: [MHCLSIG]	Not Clinically Sigficant

Row 2	
Medical History #: [MHNUM]	2
Body System Code: [MHSCAT]	Genitourinary/Renal
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	POSTMENOPAUSAL
Onset Date: [MHSTDAT]	UN-UNK-2017
Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	Yes
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 3	
Medical History #: [MHNUM]	3
Body System Code: [MHSCAT]	Cardiovascular
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	HYPERTENSION
Onset Date: [MHSTDAT]	UN-UNK-1998
Date Resolved: [MHENDAT]	UN-UNK-2015
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant

Row 4	
Medical History #: [MHNUM]	4
Body System Code: [MHSCAT]	Dermatologic
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	INTERMITTENT PSORIASIS- LEGS AND ELBOWS
Onset Date: [MHSTDAT]	UN-UNK-1980
Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	Yes
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 5	
Medical History #: [MHNUM]	5
Body System Code: [MHSCAT]	HEENT
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	MULTIPLE MISSING TEETH
Onset Date: [MHSTDAT]	UN-UNK-2000
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	scampbell@vinceandassociates.com ((b) (6) Campbell)	
Date/Time	06-Aug-2018 10:57 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
[Row 5] MHSCAT [MHSCAT]	Genitourinary/Renal	HEENT
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:42 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
MHYN [MHYN]	No	Yes
MHDAT [MHDAT]		21-May-2018
[Row 1] MHNUM [MHNUM]		1
[Row 1] MHSCAT [MHSCAT]		Immunologic/Allergies
[Row 1] MHCAT [MHSCAT]		ALLERGY PCN- HIVES
[Row 1] MHSTDAT [MHSTDAT]		UN-UNK-1974
[Row 1] MHONGO [MHONGO]		Yes
[Row 1] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 2] MHNUM [MHNUM]		2
[Row 2] MHSCAT		Genitourinary/Renal

Variable	Old Value	New Value
[MHSCAT]		
[Row 2] MHCAT [MHSCAT]		POSTMENOPAUSAL
[Row 2] MHSTDAT [MHSTDAT]		UN-UNK-2017
[Row 2] MHONGO [MHONGO]		Yes
[Row 2] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 3] MHNUM [MHNUM]		3
[Row 3] MHSCAT [MHSCAT]		Cardiovascular
[Row 3] MHCAT [MHSCAT]		HYPERTENSION
[Row 3] MHSTDAT [MHSTDAT]		UN-UNK-1998
[Row 3] MHENDAT [MHENDAT]		UN-UNK-2015
[Row 3] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 4] MHNUM [MHNUM]		4
[Row 4] MHSCAT [MHSCAT]		Dermatologic
[Row 4] MHCAT [MHSCAT]		INTERMITTENT PSORIASIS-LEGS AND ELBOWS
[Row 4] MHSTDAT [MHSTDAT]		UN-UNK-1980
[Row 4] MHONGO [MHONGO]		Yes
[Row 4] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 5] MHNUM [MHNUM]		5
[Row 5] MHSCAT [MHSCAT]		Genitourinary/Renal
[Row 5] MHCAT [MHSCAT]		MULTIPLE MISSING TEETH
[Row 5] MHSTDAT [MHSTDAT]		UN-UNK-2000
[Row 5] MHONGO [MHONGO]		Yes

Variable	Old Value	New Value
[Row 5] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:00 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
MHYN [MHYN]		No
MHSMK [MHSMK]		Yes
MHRECUSE [MHRECUSE]		No

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Medical History

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	15-Aug-2018 09:47 AM PDT (UTC-07:00)	Form marked as Complete
System	31-Jul-2018 01:50 PM PDT (UTC-07:00)	Form marked as Not Complete
System	31-May-2018 10:00 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	15-Aug-2018 09:47 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

User	Date/Time	Status
scampbell@vinceandassociates.com ((b) (6) Campbell)	06-Aug-2018 10:57 AM PDT (UTC-07:00)	Form unmarked as "Form Monitored". Data entry error
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 01:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Medical History

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 5] MHSCAT	updated [06-Aug-2018 10:58 AM by scampbell@vinceandassociates.com ((b) (6) Campbell)] Response satisfies query [15-Aug-2018 09:47 AM by (b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 01:50 PM	15-Aug-2018 09:47 AM
	Description			
	New: source is HEENT, please correct or clarify. **Old:** **By:** 31-Jul-2018 01:50 PM (b) (6) gmail.com ((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)	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]	21-May-2018
Completion Time: [PETIM]	14:33
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]	ABNORMAL NCS
Abnormal Findings: [PEDESC]	MULTIPLE MISSING TEETH
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]	ABNORMAL NCS
Abnormal Findings: [PEDESC]	PSORIASIS BOTH ARMS AND LEGS
Row 10	
Body System Examined: [PETEST]	OTHER
Not done: [PESTAT]	Yes
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	
Abnormal Findings: [PEDESC]	

AUDIT TRAIL

VISIT: Screening
FORM: Complete Physical Examination

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:42 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 2] PEORRES [PEORRES]	NORMAL	ABNORMAL NCS
[Row 2] PEDESC [PEDESC]		MULTIPLE MISSING TEETH
[Row 9] PEORRES [PEORRES]	NORMAL	ABNORMAL NCS
[Row 9] PEDESC [PEDESC]		PSORIASIS BOTH ARMS AND LEGS
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:01 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
PEYN [PEYN]		Yes
PEDAT		21-May-2018

Variable	Old Value	New Value
[PEDAT]		
PETIM [PETIM]		14:33
[Row 1] PETEST [PETEST]		GENERAL APPEARANCE
[Row 1] PEORRES [PEORRES]		NORMAL
[Row 2] PETEST [PETEST]		HEENT
[Row 2] PEORRES [PEORRES]		NORMAL
[Row 3] PETEST [PETEST]		NECK/THYROID
[Row 3] PEORRES [PEORRES]		NORMAL
[Row 4] PETEST [PETEST]		CARDIOVASCULAR
[Row 4] PEORRES [PEORRES]		NORMAL
[Row 5] PETEST [PETEST]		RESPIRATORY
[Row 5] PEORRES [PEORRES]		NORMAL
[Row 6] PETEST [PETEST]		GASTROINTESTINAL
[Row 6] PEORRES [PEORRES]		NORMAL
[Row 7] PETEST [PETEST]		NEUROLOGICAL
[Row 7] PEORRES [PEORRES]		NORMAL
[Row 8] PETEST [PETEST]		MUSCULOSKELETAL/EXTREMITIES
[Row 8] PEORRES [PEORRES]		NORMAL
[Row 9] PETEST [PETEST]		SKIN
[Row 9] PEORRES [PEORRES]		NORMAL
[Row 10] PETEST [PETEST]		OTHER
[Row 10] PESTAT [PESTAT]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Complete Physical Examination

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:01 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 01:52 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Complete Physical Examination

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

CLINICAL DATA

VISIT: Screening
FORM: Height, Weight and BMI

Was the assessment performed? [VSYN]	Yes

Visit Date: [VSDAT]	21-May-2018
Height: [VSHGT]	169.0
Weight: [VSWGT]	82.4
BMI: [VSBMI]	28.9

AUDIT TRAIL

VISIT: Screening
FORM: Height, Weight and BMI

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 11:06 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
VSHGT [VSHGT]	187.0	169.0
VSWGT [VSWGT]	75.1	82.4
VSBMI [VSBMI]	21.5	28.9
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 09:53 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
VSYN [VSYN]		Yes
VSDAT [VSDAT]		21-May-2018
VSHGT [VSHGT]		187.0
VSWGT [VSWGT]		75.1
VSBMI [VSBMI]		21.5

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	31-May-2018 09:53 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:42 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Height, Weight and BMI

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

CLINICAL DATA

VISIT: Screening
FORM: Serology Lab Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes

Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:45
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)	
Date/Time	05-Jul-2018 02:46 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
LBTIM [LBTIM]	14:39	14:45
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:00 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN [LBYN]		Yes
LBDAT [LBDAT]		21-May-2018
LBTIM [LBTIM]		14:39
LBNRIND		Yes

Variable	Old Value	New Value
[LBNRIND]		

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	31-May-2018 10:00 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:45 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Serology Lab Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Serum Pregnancy Test

Was Serum Pregnancy Test performed? [LBHCGYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:45
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	04-Jun-2018 02:53 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBHCGYN [LBHCGYN]		Yes
LBDAT1 [LBDAT]		21-May-2018
LBTIM1 [LBTIM]		14:45

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	04-Jun-2018 02:53 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 10:38 AM PDT (UTC-07:00)	Form marked as Not Complete

User	Date/Time	Change
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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".
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)	31-Jul-2018 01:53 PM 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) algopharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: Screening
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	14:34

Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	21-May-2018
Time Taken: [VSTIM]	14:39
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.6
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	134
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure

Not done: [VSSTAT]	
Result: [VSORRES]	91
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	76
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	17
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Screening
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:08 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
VSTIMS [VS1TIMS]	14:12	14:34
VSTIM [VSTIM]	14:17	14:39
[Row 1] VSORRES [VSORRES]	36.2	36.6
[Row 2] VSORRES [VSORRES]	121	134
[Row 3] VSORRES [VSORRES]	78	91
[Row 4] VSORRES [VSORRES]	56	76
[Row 5] VSORRES [VSORRES]	16	17
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 09:55 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		14:12
VS1DAT [VSDAT]		21-May-2018
VSTIM [VSTIM]		14:17
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.2
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[VSCLSIG]		
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		121
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		78
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		56
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		16
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: 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	31-May-2018 09:55 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:38 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)	30-Jul-2018 02:44 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:27
Time Unknown: [LBTMNK]	

Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 11:08 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
LBTIM3 [LBTIM]	14:03	14:27
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 09:56 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		21-May-2018
LBTIM3 [LBTIM]		14:03
LBNRIND3 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 09:56 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:38 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)	30-Jul-2018 02:44 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Cotinine Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:27
Time Unknown: [LBTMNK]	

Is the result within range? [LBNRIND]	No

Row 1	
Test Name: [LBTEST]	Cotinine
Clinical Significance as per MD: [LBCLSIG]	NCS

AUDIT TRAIL

VISIT: Screening
FORM: Cotinine Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 11:09 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
LBTIM4 [LBTIM]	14:03	14:27
LBNRIND4 [LBNRIND]	Yes	No
[Row 1] LBTEST5 [LBTEST]		Cotinine
[Row 1] LBCLSIG4 [LBCLSIG]		NCS
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 09:56 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN4 [LBYN]		Yes
LBDAT4 [LBDAT]		21-May-2018
LBTIM4 [LBTIM]		14:03
LBNRIND4 [LBNRIND]		Yes

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	31-May-2018 09:56 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:44 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Cotinine Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes

Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:45
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	No
Row 1	
Test Name: [LBTEST]	Glucose
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS
Row 2	
Test Name: [LBTEST]	Creatinine
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS

AUDIT TRAIL

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:11 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
LBTIM5 [LBTIM]	14:39	14:45
LBNRIND5 [LBNRIND]	Yes	No
[Row 1] LBTEST [LBTEST]		Glucose
[Row 1] LBCLSIG5 [LBCLSIG]		NCS

Variable	Old Value	New Value
[Row 2] LBTEST [LBTEST]		Creatinine
[Row 2] LBCLSIG5 [LBCLSIG]		NCS
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 09:58 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		21-May-2018
LBTIM5 [LBTIM]		14:39
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	31-May-2018 09:58 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:46 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Hematology Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:45
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]	RED BLOOD CELL
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	(b) (6) vinceandassociates.com ([redacted]	
Date/Time	31-May-2018 11:11 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
LBTIM6 [LBTIM]	14:39	14:45
LBNRIND6 [LBNRIND]	Yes	No
[Row 1] LBTEST6 [LBTEST]		HEMATOCRIT
[Row 1] LBCLSIG6 [LBCLSIG]		NCS
[Row 2] LBTEST6 [LBTEST]		RED BLOOD CELL
[Row 2] LBCLSIG6 [LBCLSIG]		NCS
Logged in User	(b) (6) vinceandassociates.com ([redacted]	
Date/Time	31-May-2018 09:59 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		21-May-2018
LBTIM6 [LBTIM]		14:39
LBNRIND6 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Hematology Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 09:59 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:38 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)	30-Jul-2018 02:46 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Hematology Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:27
Time Unknown: [LBTMNK]	

Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:21 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
LBTIM7 [LBTIM]	14:03	14:27
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:00 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		21-May-2018
LBTIM7 [LBTIM]		14:03
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

User	Date/Time	Change
System	31-May-2018 10:00 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:45 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Endocrinology Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:45

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: Endocrinology Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:22 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN5 [LBYN]		Yes
LBDAT8 [LBDAT]		21-May-2018
LBTIM8 [LBTIM]		14:45
LBNRIND8 [LBNRIND]		Yes

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	31-May-2018 11:22 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 10:38 AM PDT (UTC-07:00)	Form marked as Not Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	31-May-2018 09:38 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)	30-Jul-2018 02:46 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

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]	21-May-2018
Visit: [EGVIS]	Screening

Row 1	
Time: [EGTIM]	14:33
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	71
PR Interval: [EGPR]	183
QRS Interval: [EGQRS]	92
QT Interval: [EGQT]	396
QTcB Interval: [EGQTCB]	431
QTcF: [EGQTCF]	419
Clinical Significance as per MD: [EGCLSIG]	NORMAL
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Screening
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:07 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 1] EG1TIM [EGTIM]	14:10	14:33
[Row 1] EGVR [EGVR]	51	71

Variable	Old Value	New Value
[Row 1] EG1PR [EGPR]	192	183
[Row 1] EG1QRS [EGQRS]	98	92
[Row 1] EG1QT [EGQT]	397	396
[Row 1] EGQTCB [EGQTCB]	366	431
[Row 1] EG1QTCF [EGQTCF]	376	419
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 09:54 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT [EGDAT]		21-May-2018
EGVIS [EGVIS]		Screening
[Row 1] EG1TIM [EGTIM]		14:10
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		51
[Row 1] EG1PR [EGPR]		192
[Row 1] EG1QRS [EGQRS]		98
[Row 1] EG1QT [EGQT]		397
[Row 1] EGQTCB [EGQTCB]		366
[Row 1] EG1QTCF [EGQTCF]		376
[Row 1] EG1CLSIG [EGCLSIG]		NORMAL

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: ECG Test Results

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 09:54 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	30-Jul-2018 02:43 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: ECG Test Results

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	21-May-2018

Childbearing Potential: [SCSTATUS]	NON-CHILDBEARING POTENTIAL
Is subject considered post-menopausal? [SCPOST]	Yes
Last menses: [SCMENDAT]	UN-UNK-2016

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

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

AUDIT TRAIL

VISIT: Screening
FORM: Female Contraceptive Method

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:23 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SCDAT [SCDAT]		21-May-2018
SC1STATUS [SCSTATUS]		NON-CHILDBEARING POTENTIAL
SC1POST [SCPOST]		Yes
SCMENDAT [SCMENDAT]		UN-UNK-2016
[Row 1] SCSUR [SCSUR]		Post-menopausal

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	31-May-2018 11:23 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 10:38 AM PDT (UTC-07:00)	Form marked as Not Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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".
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)	30-Jul-2018 02:42 PM 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) algopharm.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-1988
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	
Daily Use: [SUDYUS]	10
Row 2	
Type of tobacco used? [SUTRT]	Cigar(s)
Frequency: [SUFRQ]	Current
Start Date: [SUSTDAT]	UN-UNK-1990
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	10

Weekly Use: [SUWKUS]	
Daily Use: [SUDYUS]	
Row 3	
Type of tobacco used? [SUTRT]	Cigarillo(s)
Frequency: [SUFRQ]	Current
Start Date: [SUSTDAT]	UN-UNK-1990
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	5
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 11:02 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-1988

Variable	Old Value	New Value
[Row 1] SUDYUS1 [SUDYUS]		10
[Row 2] SUTRT1 [SUTRT]		Cigar(s)
[Row 2] SUFRQ1 [SUFRQ]		Current
[Row 2] SUSTDAT1 [SUSTDAT]		UN-UNK-1990
[Row 2] SUMONUS1 [SUMONUS]		10
[Row 3] SUTRT1 [SUTRT]		Cigarillo(s)
[Row 3] SUFRQ1 [SUFRQ]		Current
[Row 3] SUSTDAT1 [SUSTDAT]		UN-UNK-1990
[Row 3] SUMONUS1 [SUMONUS]		5
[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
[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

User	Date/Time	Change
System	16-Jul-2018 09:27 AM PDT (UTC-07:00)	Form marked as Complete
System	11-Jul-2018 11:02 AM PDT (UTC-07:00)	Form marked as Not Complete
System	11-Jul-2018 11:02 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)	30-Jul-2018 02:41 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Tobacco Use

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 3] SUYRUS1	NOT APPLICABLE [11-Jul-2018 11:03 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM
	Description			
	New: Yearly Use is missing, please review			

ID	Variable	Responses/Reasons	Opened	Closed
	Old: **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 2] SUYRUS1	NOT APPLICABLE [11-Jul-2018 11:03 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM
	Description			
	New: Yearly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] SUYRUS1	NOT APPLICABLE [11-Jul-2018 11:02 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM
	Description			
	New: Yearly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 3] SUWKUS1	NOT APPLICABLE [11-Jul-2018 11:04 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM

ID	Variable	Responses/Reasons	Opened	Closed
		[16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)		
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 2] SUWKUS1	NOT APPLICABLE [11-Jul-2018 11:03 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] SUWKUS1	NOT APPLICABLE [11-Jul-2018 11:03 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] SUMONUS1	NOT APPLICABLE [11-Jul-2018 11:03 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM
	Description			
	New: Monthly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 3] SUDYUS1	NOT APPLICABLE [11-Jul-2018 11:04 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM
	Description			
	New: Daily Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 AM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 2] SUDYUS1	NOT APPLICABLE [11-Jul-2018 11:03 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [16-Jul-2018 09:27 AM by (b) (6) vinceandass	11-Jul-2018 11:02 AM	16-Jul-2018 09:27 AM

ID	Variable	Responses/Reasons	Opened	Closed
		ociates.com ((b) (6) (b) (6)		
	Description			
	New: Daily Use is missing, please review **Old:** **By:** 11-Jul-2018 11:02 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]	25-May-2018

AUDIT TRAIL

VISIT: Day -1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:01 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		25-May-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	31-May-2018 10:01 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 01:53 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day -1
FORM: Urine Pregnancy Test

Was Urine Pregnancy Test performed? [LBHCGYN]	Yes

Date of collection: [LBDAT]	25-May-2018
Time of Collection: [LBTIM]	07:20
Time Unknown: [LBTMNK]	

AUDIT TRAIL

VISIT: Day -1
FORM: Urine Pregnancy Test

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 11:24 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBHCGYN1 [LBHCGYN]		Yes
LBDAT2 [LBDAT]		25-May-2018
LBTIM2 [LBTIM]		07:20

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	31-May-2018 11:24 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 10:38 AM PDT (UTC-07:00)	Form marked as Not Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	31-Jul-2018 01:55 PM 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]	07:26
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	25-May-2018

Time Taken: [VSTIM]	07:34
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	37.3
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	135
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	90

Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	82
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	15
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Day -1
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:25 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
VSTIMS	15:25	07:26

Variable	Old Value	New Value
[VS1TIMS]		
VSTIM [VSTIM]	15:30	07:34
[Row 1] VSORRES [VSORRES]	36.5	37.3
[Row 2] VSORRES [VSORRES]	125	135
[Row 3] VSORRES [VSORRES]	79	90
[Row 4] VSORRES [VSORRES]	50	82
[Row 5] VSORRES [VSORRES]	17	15
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:05 AM PDT (UTC-07:00)	

Variable	Old Value	New Value
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		15:25
VS1DAT [VSDAT]		25-May-2018
VSTIM [VSTIM]		15:30
[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]		125
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		79
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		50
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		17
[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	31-May-2018 10:05 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Vital Signs

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 01:55 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Vital Signs

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

CLINICAL DATA

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

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	25-May-2018
Time of Collection: [LBTIM]	07:20
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 11:24 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
LBTIM3 [LBTIM]	07:37	07:20
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:07 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		25-May-2018
LBTIM3 [LBTIM]		07:37
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	31-May-2018 10:07 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 01:54 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

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

AUDIT TRAIL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:07 AM PDT (UTC-07:00)	
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	31-May-2018 10:07 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 01:56 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

VISIT: Day 1
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:08 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN		Yes

Variable	Old Value	New Value
[SVYN]		
SVSTDAT [SVSTDAT]		26-May-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	31-May-2018 10:08 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 01:56 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Visit Date

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
(b) (6) vinceandassociates.com ((b) (6)	05-Jun-2018 12:14 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

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

CLINICAL DATA

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

AD LIB VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG	
Date of Visit: [EXDAT]	26-May-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:10
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:14
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:33
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:39

Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:09
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:16
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:59
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:06
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:45
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:51

Row 6	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:19
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:26
Row 7	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:51
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:59

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	05-Jun-2018 12:14 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT1 [EXDAT]		26-May-2018
[Row 1] EXPRDT1 [EXPRDT]		Combustible Cigarette

Variable	Old Value	New Value
[Row 1] EXDSPD1 [EXDSPD]		1
[Row 1] EXTIM1 [EXTIM]		09:10
[Row 1] EXCIGRET1 [EXCIGRET]		1
[Row 1] EXTIMRET1 [EXTIMRET]		09:14
[Row 2] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD1 [EXDSPD]		1
[Row 2] EXTIM1 [EXTIM]		09:33
[Row 2] EXCIGRET1 [EXCIGRET]		1
[Row 2] EXTIMRET1 [EXTIMRET]		09:39
[Row 3] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD1 [EXDSPD]		1
[Row 3] EXTIM1 [EXTIM]		10:09
[Row 3] EXCIGRET1 [EXCIGRET]		1
[Row 3] EXTIMRET1 [EXTIMRET]		10:16
[Row 4] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD1 [EXDSPD]		1
[Row 4] EXTIM1 [EXTIM]		10:59
[Row 4] EXCIGRET1 [EXCIGRET]		1
[Row 4] EXTIMRET1 [EXTIMRET]		11:06
[Row 5] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD1 [EXDSPD]		1

Variable	Old Value	New Value
[Row 5] EXTIM1 [EXTIM]		11:45
[Row 5] EXCIGRET1 [EXCIGRET]		1
[Row 5] EXTIMRET1 [EXTIMRET]		11:51
[Row 6] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD1 [EXDSPD]		1
[Row 6] EXTIM1 [EXTIM]		12:19
[Row 6] EXCIGRET1 [EXCIGRET]		1
[Row 6] EXTIMRET1 [EXTIMRET]		12:26
[Row 7] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD1 [EXDSPD]		1
[Row 7] EXTIM1 [EXTIM]		12:51
[Row 7] EXCIGRET1 [EXCIGRET]		1
[Row 7] EXTIMRET1 [EXTIMRET]		12:59

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	05-Jun-2018 12:14 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 02:02 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG	
Date of Visit: [EXDAT]	
Row 1	
Product Used: [EXPRDT]	
Number Dispensed: [EXDSPD]	

Time Dispensed: [EXTIM]	
Number of Pieces Returned: [EXNICRET]	
Time Returned/Discarded: [EXTIMRET]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	05-Jun-2018 12:14 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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]	26-May-2018
Randomization Number: [DSNUM]	1019
Sequence Group [DSRNGRP]	ABC

AUDIT TRAIL

VISIT: Day 1
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 07:28 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
DSRNGRP [DSRNGRP]		ABC
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:25 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
DSRNUM [DSNUM]	1030	1019
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:09 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		26-May-2018
DSRNUM [DSNUM]		1030

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	31-May-2018 10:09 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 01:57 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Randomization

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	07-Jun-2018 07:31 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 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	07-Jun-2018 07:31 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
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]	31-Jul-2018 01:57 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Use Product Again - VAS

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

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

AUDIT TRAIL

VISIT: Day 2
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:09 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		27-May-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	31-May-2018 10:09 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:05 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 2
FORM: Visit Date

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	27-May-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1

Time Dispensed: [EXTIM]	09:10
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:16
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:28
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:34
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:19
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:25
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:59

Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:06
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:59
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:05
Row 6	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:20
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:25
Row 7	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:45
Number of Butts Returned: [EXCIGRET]	1

Time Returned: [EXTIMRET]	12:51
Row 8	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:58
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:03
Row 9	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:04
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:10

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 07:42 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] EXTIM	13:04	09:10

Variable	Old Value	New Value
[EXTIM]		
[Row 1] EXTIMRET [EXTIMRET]	13:10	09:16
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1
[Row 2] EXTIM [EXTIM]		09:28
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		09:34
[Row 3] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		10:19
[Row 3] EXCIGRET [EXCIGRET]		1
[Row 3] EXTIMRET [EXTIMRET]		10:25
[Row 4] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		10:59
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		11:06
[Row 5] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD [EXDSPD]		1
[Row 5] EXTIM [EXTIM]		11:59
[Row 5] EXCIGRET [EXCIGRET]		1
[Row 5] EXTIMRET [EXTIMRET]		12:05

Variable	Old Value	New Value
[Row 6] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD [EXDSPD]		1
[Row 6] EXTIM [EXTIM]		12:20
[Row 6] EXCIGRET [EXCIGRET]		1
[Row 6] EXTIMRET [EXTIMRET]		12:25
[Row 7] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD [EXDSPD]		1
[Row 7] EXTIM [EXTIM]		12:45
[Row 7] EXCIGRET [EXCIGRET]		1
[Row 7] EXTIMRET [EXTIMRET]		12:51
[Row 8] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 8] EXDSPD [EXDSPD]		1
[Row 8] EXTIM [EXTIM]		12:58
[Row 8] EXCIGRET [EXCIGRET]		1
[Row 8] EXTIMRET [EXTIMRET]		13:03
[Row 9] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 9] EXDSPD [EXDSPD]		1
[Row 9] EXTIM [EXTIM]		13:04
[Row 9] EXCIGRET [EXCIGRET]		1
[Row 9] EXTIMRET [EXTIMRET]		13:10
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 07:35 AM PDT (UTC-07:00)	

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		27-May-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM [EXTIM]		13:04
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		13:10
Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6)	
Date/Time	07-Jun-2018 07:32 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Database update	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]	27-May-2018	
[Row 1] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 1] EXDSPD [EXDSPD]	1	
[Row 1] EXTIM [EXTIM]	09:10	
[Row 1] EXCIGRET [EXCIGRET]	1	
[Row 1] EXTIMRET [EXTIMRET]	09:16	
[Row 2] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 2] EXDSPD [EXDSPD]	1	
[Row 2] EXTIM [EXTIM]	09:28	
[Row 2] EXCIGRET [EXCIGRET]	1	
[Row 2] EXTIMRET	09:34	

Variable	Old Value	New Value
[EXTIMRET]		
[Row 3] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 3] EXDSPD [EXDSPD]	1	
[Row 3] EXTIM [EXTIM]	10:19	
[Row 3] EXCIGRET [EXCIGRET]	1	
[Row 3] EXTIMRET [EXTIMRET]	10:25	
[Row 4] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 4] EXDSPD [EXDSPD]	1	
[Row 4] EXTIM [EXTIM]	10:59	
[Row 4] EXCIGRET [EXCIGRET]	1	
[Row 4] EXTIMRET [EXTIMRET]	11:06	
[Row 5] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 5] EXDSPD [EXDSPD]	1	
[Row 5] EXTIM [EXTIM]	11:59	
[Row 5] EXCIGRET [EXCIGRET]	1	
[Row 5] EXTIMRET [EXTIMRET]	12:05	
[Row 6] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 6] EXDSPD [EXDSPD]	1	
[Row 6] EXTIM [EXTIM]	12:20	
[Row 6] EXCIGRET [EXCIGRET]	1	
[Row 6] EXTIMRET [EXTIMRET]	12:25	
[Row 7] EXPRDT [EXPRDT]	Combustible Cigarette	

Variable	Old Value	New Value
[Row 7] EXDSPD [EXDSPD]	1	
[Row 7] EXTIM [EXTIM]	12:45	
[Row 7] EXCIGRET [EXCIGRET]	1	
[Row 7] EXTIMRET [EXTIMRET]	12:51	
[Row 8] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 8] EXDSPD [EXDSPD]	1	
[Row 8] EXTIM [EXTIM]	12:58	
[Row 8] EXCIGRET [EXCIGRET]	1	
[Row 8] EXTIMRET [EXTIMRET]	13:03	
[Row 9] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 9] EXDSPD [EXDSPD]	1	
[Row 9] EXTIM [EXTIM]	13:04	
[Row 9] EXCIGRET [EXCIGRET]	1	
[Row 9] EXTIMRET [EXTIMRET]	13:10	
[Row 10] EXPRDT [EXPRDT]	Combustible Cigarette	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	05-Jun-2018 01:17 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		27-May-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM		09:10

Variable	Old Value	New Value
[EXTIM]		
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		09:16
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1
[Row 2] EXTIM [EXTIM]		09:28
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		09:34
[Row 3] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		10:19
[Row 3] EXCIGRET [EXCIGRET]		1
[Row 3] EXTIMRET [EXTIMRET]		10:25
[Row 4] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		10:59
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		11:06
[Row 5] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD [EXDSPD]		1
[Row 5] EXTIM [EXTIM]		11:59
[Row 5] EXCIGRET [EXCIGRET]		1

Variable	Old Value	New Value
[Row 5] EXTIMRET [EXTIMRET]		12:05
[Row 6] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD [EXDSPD]		1
[Row 6] EXTIM [EXTIM]		12:20
[Row 6] EXCIGRET [EXCIGRET]		1
[Row 6] EXTIMRET [EXTIMRET]		12:25
[Row 7] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD [EXDSPD]		1
[Row 7] EXTIM [EXTIM]		12:45
[Row 7] EXCIGRET [EXCIGRET]		1
[Row 7] EXTIMRET [EXTIMRET]		12:51
[Row 8] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 8] EXDSPD [EXDSPD]		1
[Row 8] EXTIM [EXTIM]		12:58
[Row 8] EXCIGRET [EXCIGRET]		1
[Row 8] EXTIMRET [EXTIMRET]		13:03
[Row 9] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 9] EXDSPD [EXDSPD]		1
[Row 9] EXTIM [EXTIM]		13:04
[Row 9] EXCIGRET [EXCIGRET]		1
[Row 9] EXTIMRET [EXTIMRET]		13:10

Variable	Old Value	New Value
[Row 10] EXPRDT [EXPRDT]		Combustible Cigarette

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 07:35 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:17 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:17 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FIELD STATUSES

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

Variable	Row Number	User	Date/Time	Field status
EXPRDT	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared

Variable	Row Number	User	Date/Time	Field status
EXPRDT	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared

Variable	Row Number	User	Date/Time	Field status
EXTIM	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared

Variable	Row Number	User	Date/Time	Field status
EXCIGRET	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared

Variable	Row Number	User	Date/Time	Field status
EXTIMRET	2	(b) (6) vinceandassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	1	(b) (6) vinceandassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared
EXDAT		(b) (6) vinceandassociates.com (b) (6) (b) (6)	07-Jun-2018 07:32 AM PDT (UTC-07:00)	The status was set to Cleared

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:03 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

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

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 10] EXTIMRET	Invalidated by clearing the form [07-Jun-2018 07:32 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	05-Jun-2018 01:17 PM	07-Jun-2018 07:32 AM
	Description			
	New: Time Returned is missing, please review **Old:** **By:** 05-Jun-2018 01:17 PM (b) (6) vinceandassociates.com (b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 10] EXTIM	Invalidated by clearing the form [07-Jun-2018 07:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	05-Jun-2018 01:17 PM	07-Jun-2018 07:32 AM
	Description			
	New: Time Dispenses is missing, please review **Old:** **By:** 05-Jun-2018 01:17 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 10] EXCIGRET	Invalidated by clearing the form [07-Jun-2018 07:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	05-Jun-2018 01:17 PM	07-Jun-2018 07:32 AM
	Description			
	New: Number of Butts returned is missing, please review **Old:** **By:** 05-Jun-2018 01:17 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 10] EXDSPD	Invalidated by clearing the form [07-Jun-2018 07:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	05-Jun-2018 01:17 PM	07-Jun-2018 07:32 AM
	Description			
	New: Number dispensed is missing, please review **Old:** **By:** 05-Jun-2018 01:17 PM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	05-Jun-2018 01:18 PM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
(b) (6) vinceandassociates.com ((b) (6)	05-Jun-2018 01:18 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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)	
Date/Time	07-Jun-2018 07:37 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Use Product Again - VAS

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 07:37 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM 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)	31-Jul-2018 02:05 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 2
FORM: Use Product Again - VAS

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

CLINICAL DATA

VISIT: Day 3
FORM: Visit Date

Visit Done? [SVYN]	Yes

Date of Visit: [SVSTDAT]	28-May-2018

AUDIT TRAIL

VISIT: Day 3
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:10 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		28-May-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	31-May-2018 10:10 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:06 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 3
FORM: Visit Date

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

CLINICAL DATA

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

AD LIB USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG	
Date of Visit: [EXDAT]	
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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	29-May-2018 11:41 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	29-May-2018 11:41 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG	
Date of Visit: [EXDAT]	28-May-2018
Row 1	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:10
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	09:22

Row 2	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:37
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	10:46
Row 3	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:32
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	12:41

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 07:45 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT2 [EXDAT]		28-May-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]		09:10
[Row 1] EXNICRET [EXNICRET]		1
[Row 1] EXTIMRET2 [EXTIMRET]		09:22
[Row 2] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 2] EXDSPD2 [EXDSPD]		1
[Row 2] EXTIM2 [EXTIM]		10:37
[Row 2] EXNICRET [EXNICRET]		1
[Row 2] EXTIMRET2 [EXTIMRET]		10:46
[Row 3] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 3] EXDSPD2 [EXDSPD]		1
[Row 3] EXTIM2 [EXTIM]		12:32
[Row 3] EXNICRET [EXNICRET]		1
[Row 3] EXTIMRET2 [EXTIMRET]		12:41

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 07:45 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 07:28 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	29-May-2018 11:41 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
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)	31-Jul-2018 02:07 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 3
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 3
FORM: Use Product Again - VAS

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	07-Jun-2018 07:46 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	07-Jun-2018 07:46 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM 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]	31-Jul-2018 02:06 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 3
FORM: Use Product Again - VAS

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

CLINICAL DATA

VISIT: Day 4
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	29-May-2018

AUDIT TRAIL

VISIT: Day 4
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:10 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		29-May-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	31-May-2018 10:10 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:08 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 4
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day 4
FORM: Randomization

Date of Randomization: [DSRDAT]	29-May-2018
Randomization Number: [DSNUM]	2019
Sequence Group [DSRNGRP]	BCA

AUDIT TRAIL

VISIT: Day 4
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	07-Jun-2018 08:12 AM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
DSRNGRP [DSRNGRP]		BCA
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 11:26 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
DSRNUM [DSNUM]	2030	2019
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:10 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		29-May-2018
DSRNUM [DSNUM]		2030

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	31-May-2018 10:10 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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".

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)	31-Jul-2018 02:08 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 4
FORM: Randomization

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

CLINICAL DATA

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

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	
Row 1	
Product: [EXPRDB]	
Session Start Time: [EXSRTTIMB]	
Session End Time: [EXENTMB]	

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Expected
System	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algopharm.com (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	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Expected
System	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	

Date of Visit: [EXDATB]	29-May-2018
Session Start Time: [EXSRTTIM]	15:10
Session End Time: [EXENDTIM]	15:16
Row 1	
Inhalation Begin: [EXINHBG]	15:10:00
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:02
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:10:06
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:07
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:10:25
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:27
Time Unknown: [EXTIMUNK]	

Row 4	
Inhalation Begin: [EXINHBG]	15:10:38
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:40
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:10:51
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:52
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:11:22
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:23
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:11:34
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:36

Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:11:48
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:49
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:12:00
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:12:02
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:12:19
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:12:20
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	15:12:53
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	15:12:54
Time Unknown: [EXTIMUNK]	
Row 12	
Inhalation Begin: [EXINHBG]	15:13:07
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:08
Time Unknown: [EXTIMUNK]	
Row 13	
Inhalation Begin: [EXINHBG]	15:13:40
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:42
Time Unknown: [EXTIMUNK]	
Row 14	
Inhalation Begin: [EXINHBG]	15:13:49
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:50
Time Unknown: [EXTIMUNK]	
Row 15	
Inhalation Begin: [EXINHBG]	15:14:47

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:14:48
Time Unknown: [EXTIMUNK]	
Row 16	
Inhalation Begin: [EXINHBG]	15:15:59
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:16:00
Time Unknown: [EXTIMUNK]	
Row 17	
Inhalation Begin: [EXINHBG]	15:16:32
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:16:33
Time Unknown: [EXTIMUNK]	
Row 18	
Inhalation Begin: [EXINHBG]	15:16:37
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:16:38
Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	18

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 12:54 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 16] EXINEN [EXINEN]		15:16:00
[Row 16] EXTIMUNK4 [EXTIMUNK]	Yes	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 12:49 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 16] EXTIMUNK4 [EXTIMUNK]		Yes
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 08:30 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATB [EXDATB]		29-May-2018
EXSRTTIM [EXSRTTIM]		15:10
EXENDTIM [EXENDTIM]		15:16
[Row 1] EXINHBG [EXINHBG]		15:10:00

Variable	Old Value	New Value
[Row 1] EXINEN [EXINEN]		15:10:02
[Row 2] EXINHBG [EXINHBG]		15:10:06
[Row 2] EXINEN [EXINEN]		15:10:07
[Row 3] EXINHBG [EXINHBG]		15:10:25
[Row 3] EXINEN [EXINEN]		15:10:27
[Row 4] EXINHBG [EXINHBG]		15:10:38
[Row 4] EXINEN [EXINEN]		15:10:40
[Row 5] EXINHBG [EXINHBG]		15:10:51
[Row 5] EXINEN [EXINEN]		15:10:52
[Row 6] EXINHBG [EXINHBG]		15:11:22
[Row 6] EXINEN [EXINEN]		15:11:23
[Row 7] EXINHBG [EXINHBG]		15:11:34
[Row 7] EXINEN [EXINEN]		15:11:36
[Row 8] EXINHBG [EXINHBG]		15:11:48
[Row 8] EXINEN [EXINEN]		15:11:49
[Row 9] EXINHBG [EXINHBG]		15:12:00
[Row 9] EXINEN [EXINEN]		15:12:02
[Row 10] EXINHBG [EXINHBG]		15:12:19
[Row 10] EXINEN [EXINEN]		15:12:20
[Row 11] EXINHBG [EXINHBG]		15:12:53
[Row 11] EXINEN [EXINEN]		15:12:54

Variable	Old Value	New Value
[Row 12] EXINHBG [EXINHBG]		15:13:07
[Row 12] EXINEN [EXINEN]		15:13:08
[Row 13] EXINHBG [EXINHBG]		15:13:40
[Row 13] EXINEN [EXINEN]		15:13:42
[Row 14] EXINHBG [EXINHBG]		15:13:49
[Row 14] EXINEN [EXINEN]		15:13:50
[Row 15] EXINHBG [EXINHBG]		15:14:47
[Row 15] EXINEN [EXINEN]		15:14:48
[Row 16] EXINHBG [EXINHBG]		15:15:59
[Row 17] EXINHBG [EXINHBG]		15:16:32
[Row 17] EXINEN [EXINEN]		15:16:33
[Row 18] EXINHBG [EXINHBG]		15:16:37
[Row 18] EXINEN [EXINEN]		15:16:38
EXBEVB [EXBEVB]		No
EXINTOT [EXINTOT]		18

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 12:49 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 08:12 AM PDT (UTC-07:00)	Form marked as Not Complete

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 02:21 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

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

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 16] EXINEN	Data Updated [28-Jun-2018 12:49 PM by (b) (6) vinceandassociates.com ((b) (6)	07-Jun-2018 08:30 AM	28-Jun-2018 12:49 PM
	Description			
	New: Inhalation End is missing, please review **Old:** **By:** 07-Jun-2018 08:30 AM (b) (6) vinceandassociates.com ((b) (6)			

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]	29-May-2018
Session Start Time: [EXSTTIM]	09:10
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:10:00
Puff End: [EXPFEN]	09:10:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2

Puff Begin: [EXPFBG]	09:10:30
Puff End: [EXPFEN]	09:10:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:11:00
Puff End: [EXPFEN]	09:11:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:11:30
Puff End: [EXPFEN]	09:11:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:12:00

Puff End: [EXPFEN]	09:12:02
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:12:31
Puff End: [EXPFEN]	09:12:36
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:13:00
Puff End: [EXPFEN]	09:13:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:13:31
Puff End: [EXPFEN]	09:13:34

Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:14:00
Puff End: [EXPFEN]	09:14:02
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 10	
Puff: [EXPFF]	Puff 10
Puff Begin: [EXPFBG]	09:14:30
Puff End: [EXPFEN]	09:14:33
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 4
FORM: Part B - Controlled Usual Brand Dosing Log

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	07-Jun-2018 08:21 AM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX8DATVLN [EXDATVLN]		29-May-2018
EX8STTIM [EXSTTIM]		09:10
[Row 1] EX8PFF [EXPFF]		Puff 1
[Row 1] EX8PFBG [EXPFBG]		09:10:00
[Row 1] EX8PFEN [EXPFEN]		09:10:04
[Row 1] EX8MISPF [EXMISPF]		No
[Row 2] EX8PFF [EXPFF]		Puff 2
[Row 2] EX8PFBG [EXPFBG]		09:10:30
[Row 2] EX8PFEN [EXPFEN]		09:10:33
[Row 2] EX8MISPF [EXMISPF]		No
[Row 3] EX8PFF [EXPFF]		Puff 3
[Row 3] EX8PFBG [EXPFBG]		09:11:00
[Row 3] EX8PFEN [EXPFEN]		09:11:03
[Row 3] EX8MISPF [EXMISPF]		No
[Row 4] EX8PFF [EXPFF]		Puff 4
[Row 4] EX8PFBG [EXPFBG]		09:11:30
[Row 4] EX8PFEN [EXPFEN]		09:11:33
[Row 4] EX8MISPF [EXMISPF]		No
[Row 5] EX8PFF [EXPFF]		Puff 5
[Row 5] EX8PFBG [EXPFBG]		09:12:00

Variable	Old Value	New Value
[Row 5] EX8PFEN [EXPFEN]		09:12:02
[Row 5] EX8MISPF [EXMISPF]		No
[Row 6] EX8PFF [EXPFF]		Puff 6
[Row 6] EX8PFBG [EXPFBG]		09:12:31
[Row 6] EX8PFEN [EXPFEN]		09:12:36
[Row 6] EX8MISPF [EXMISPF]		No
[Row 7] EX8PFF [EXPFF]		Puff 7
[Row 7] EX8PFBG [EXPFBG]		09:13:00
[Row 7] EX8PFEN [EXPFEN]		09:13:03
[Row 7] EX8MISPF [EXMISPF]		No
[Row 8] EX8PFF [EXPFF]		Puff 8
[Row 8] EX8PFBG [EXPFBG]		09:13:31
[Row 8] EX8PFEN [EXPFEN]		09:13:34
[Row 8] EX8MISPF [EXMISPF]		No
[Row 9] EX8PFF [EXPFF]		Puff 9
[Row 9] EX8PFBG [EXPFBG]		09:14:00
[Row 9] EX8PFEN [EXPFEN]		09:14:02
[Row 9] EX8MISPF [EXMISPF]		No
[Row 10] EX8PFF [EXPFF]		Puff 10
[Row 10] EX8PFBG [EXPFBG]		09:14:30
[Row 10] EX8PFEN [EXPFEN]		09:14:33

Variable	Old Value	New Value
[Row 10] EX8MISPF [EXMISPF]		No
EX8BEVB [EXBEVB]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 08:12 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 02:18 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	
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 4
FORM: Part B - Controlled VLN Dosing Log

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	
Date of Visit: [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 VLN Dosing Log

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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: 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) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:09 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 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	04-Jun-2018 03:09 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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".

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)	31-Jul-2018 02:15 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 4
FORM: 2nd Use - 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) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:10 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 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	04-Jun-2018 03:10 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:16 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 02:55 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 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	04-Jun-2018 02:55 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:16 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Use: [QSUSE]	2nd Use

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

AUDIT TRAIL

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

Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	04-Jun-2018 02:56 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
QSUSE2 [QSUSE]		2nd Use
Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	04-Jun-2018 02:56 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF2 [QSPERF]		Yes

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	04-Jun-2018 02:56 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	04-Jun-2018 02:56 PM PDT (UTC-07:00)	Form marked as Not Complete
System	04-Jun-2018 02:56 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 02:16 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

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

ID	Variable	Responses/Reasons	Opened	Closed
	QSUSE2	Data Updated [04-Jun-2018 02:56 PM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	04-Jun-2018 02:56 PM	04-Jun-2018 02:56 PM
	Description			
	New: Use is missing, please review **Old:** **By:** 04-Jun-2018 02:56 PM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)			

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]	29-May-2018
Time: [PKTIM]	09:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:12

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	09:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	10:42
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	12:10
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) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:04 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]		29-May-2018
[Row 1] PKTIM [PKTIM]		09:05
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		29-May-2018
[Row 2] PKTIM [PKTIM]		09:12
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		29-May-2018
[Row 3] PKTIM [PKTIM]		09:15
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		29-May-2018
[Row 4] PKTIM [PKTIM]		09:17
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT		29-May-2018

Variable	Old Value	New Value
[PKDAT]		
[Row 5] PKTIM [PKTIM]		09:20
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		29-May-2018
[Row 6] PKTIM [PKTIM]		09:22
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		29-May-2018
[Row 7] PKTIM [PKTIM]		09:25
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		29-May-2018
[Row 8] PKTIM [PKTIM]		09:30
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		29-May-2018
[Row 9] PKTIM [PKTIM]		09:41
[Row 9] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		29-May-2018
[Row 10] PKTIM [PKTIM]		09:55
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		29-May-2018
[Row 11] PKTIM [PKTIM]		10:10
[Row 12] PKTPT [PKTPT]		90 minute

Variable	Old Value	New Value
[Row 12] PKDAT [PKDAT]		29-May-2018
[Row 12] PKTIM [PKTIM]		10:42
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		29-May-2018
[Row 13] PKTIM [PKTIM]		11:11
[Row 13] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		29-May-2018
[Row 14] PKTIM [PKTIM]		11:40
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		29-May-2018
[Row 15] PKTIM [PKTIM]		12:10

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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Complete
System	04-Jun-2018 03:04 PM PDT (UTC-07:00)	Form marked as Not Complete
System	04-Jun-2018 03:04 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:12 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:05

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:26
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:40

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	15:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	16:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	16:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	18:12
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) (b) (6)	
Date/Time	02-Jul-2018 04:48 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 7] PKCODE1 [PKCODE]		B - Late due to previous procedure
Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:09 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)

Variable	Old Value	New Value
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		29-May-2018
[Row 1] PKTIM1 [PKTIM]		15:05
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		29-May-2018
[Row 2] PKTIM1 [PKTIM]		15:12
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		29-May-2018
[Row 3] PKTIM1 [PKTIM]		15:15
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		29-May-2018
[Row 4] PKTIM1 [PKTIM]		15:17
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		29-May-2018
[Row 5] PKTIM1 [PKTIM]		15:20
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		29-May-2018
[Row 6] PKTIM1 [PKTIM]		15:22
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		29-May-2018
[Row 7] PKTIM1 [PKTIM]		15:26

Variable	Old Value	New Value
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		29-May-2018
[Row 8] PKTIM1 [PKTIM]		15:30
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		29-May-2018
[Row 9] PKTIM1 [PKTIM]		15:40
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		29-May-2018
[Row 10] PKTIM1 [PKTIM]		15:55
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		29-May-2018
[Row 11] PKTIM1 [PKTIM]		16:12
[Row 11] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		29-May-2018
[Row 12] PKTIM1 [PKTIM]		16:41
[Row 12] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		29-May-2018
[Row 13] PKTIM1 [PKTIM]		17:10
[Row 14] PKTPT1 [PKTPT]		150 minute

Variable	Old Value	New Value
[Row 14] PKDAT1 [PKDAT]		29-May-2018
[Row 14] PKTIM1 [PKTIM]		17:40
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		29-May-2018
[Row 15] PKTIM1 [PKTIM]		18:12
[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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Complete
System	04-Jun-2018 03:09 PM PDT (UTC-07:00)	Form marked as Not Complete
System	04-Jun-2018 03:09 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:13 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jun-2018 10:18 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	12-Jun-2018 10:18 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	05-Jun-2018 01:42 PM 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)	31-Jul-2018 02:15 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	12-Jun-2018 10:18 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	12-Jun-2018 10:18 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM 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**
[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]	31-Jul-2018 02:15 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	30-May-2018

AUDIT TRAIL

VISIT: Day 5
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:11 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		30-May-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	31-May-2018 10:11 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:21 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 5
FORM: Visit Date

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

CLINICAL DATA

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

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	30-May-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	09:10

Session End Time: [EXENTMB]	09:20

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 08:31 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT [EXNICDAT]		30-May-2018
[Row 1] EXPRDB [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB [EXSRTTIMB]		09:10
[Row 1] EXENTMB [EXENTMB]		09:20
EXBEV [EXBEV]		No

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 08:31 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:27 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	30-May-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	15:10

Session End Time: [EXENTMB]	15:18

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 08:32 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT2 [EXNICDAT]		30-May-2018
[Row 1] EXPRDB2 [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB2 [EXSRTTIMB]		15:10
[Row 1] EXENTMB2 [EXENTMB]		15:18
EXBEV2 [EXBEV]		No

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 08:32 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 08:12 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:27 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	
Session Start Time: [EXSRTTIM]	
Session End Time: [EXENDTIM]	

Row 1	
Inhalation Begin: [EXINHBG]	
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	
Time Unknown: [EXTIMUNK]	

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	
Session Start Time: [EXSTTIM]	

Row 1	
Puff: [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 5
FORM: Part B - Controlled Usual Brand Dosing Log

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Expected
System	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM 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	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Expected
System	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

Was Questionnaire performed at all time points: [QSPERF]	Yes
Use: [QSUSE]	1st Use

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

AUDIT TRAIL

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

Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:11 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 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	04-Jun-2018 03:11 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:38 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)	31-Jul-2018 02:25 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Completed: [QSYN]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:11 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 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	04-Jun-2018 03:11 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:25 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 5
FORM: 1st Use - 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) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:11 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF_1		Yes

Variable	Old Value	New Value
[QSPERF]		
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	04-Jun-2018 03:11 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:25 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	04-Jun-2018 03:11 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 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	04-Jun-2018 03:11 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:38 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)	31-Jul-2018 02:26 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	30-May-2018

Time: [PKTIM]	09:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:22
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	30-May-2018

Time: [PKTIM]	09:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	09:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	10:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:40
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	12:10
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) (b) (6)	
Date/Time	04-Jun-2018 03:14 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]		30-May-2018
[Row 1] PKTIM [PKTIM]		09:05
[Row 2] PKTPT [PKTPT]		2 minute

Variable	Old Value	New Value
[Row 2] PKDAT [PKDAT]		30-May-2018
[Row 2] PKTIM [PKTIM]		09:12
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		30-May-2018
[Row 3] PKTIM [PKTIM]		09:15
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		30-May-2018
[Row 4] PKTIM [PKTIM]		09:17
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		30-May-2018
[Row 5] PKTIM [PKTIM]		09:20
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		30-May-2018
[Row 6] PKTIM [PKTIM]		09:22
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		30-May-2018
[Row 7] PKTIM [PKTIM]		09:25
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		30-May-2018
[Row 8] PKTIM [PKTIM]		09:30
[Row 9] PKTPT [PKTPT]		30 minute

Variable	Old Value	New Value
[Row 9] PKDAT [PKDAT]		30-May-2018
[Row 9] PKTIM [PKTIM]		09:40
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		30-May-2018
[Row 10] PKTIM [PKTIM]		09:55
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		30-May-2018
[Row 11] PKTIM [PKTIM]		10:10
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		30-May-2018
[Row 12] PKTIM [PKTIM]		10:41
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		30-May-2018
[Row 13] PKTIM [PKTIM]		11:10
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		30-May-2018
[Row 14] PKTIM [PKTIM]		11:40
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		30-May-2018
[Row 15] PKTIM [PKTIM]		12:10

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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Complete
System	04-Jun-2018 03:14 PM PDT (UTC-07:00)	Form marked as Not Complete
System	04-Jun-2018 03:14 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 02:22 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	14:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute

Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:16
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:26
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:30

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	15:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute

Date: [PKDAT]	30-May-2018
Time: [PKTIM]	16:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	16:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	18:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) [redacted] vinceandassociates.com (b) (6) (b) (6) (b) (6)
Date/Time	04-Jun-2018 03:17 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]		30-May-2018
[Row 1] PKTIM1 [PKTIM]		14:05
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		30-May-2018
[Row 2] PKTIM1 [PKTIM]		15:12
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		30-May-2018
[Row 3] PKTIM1 [PKTIM]		15:16
[Row 3] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		30-May-2018
[Row 4] PKTIM1 [PKTIM]		15:17
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		30-May-2018
[Row 5] PKTIM1 [PKTIM]		15:20
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		30-May-2018
[Row 6] PKTIM1 [PKTIM]		15:22

Variable	Old Value	New Value
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		30-May-2018
[Row 7] PKTIM1 [PKTIM]		15:26
[Row 7] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		30-May-2018
[Row 8] PKTIM1 [PKTIM]		15:30
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		30-May-2018
[Row 9] PKTIM1 [PKTIM]		15:41
[Row 9] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		30-May-2018
[Row 10] PKTIM1 [PKTIM]		15:55
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		30-May-2018
[Row 11] PKTIM1 [PKTIM]		16:10
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		30-May-2018
[Row 12] PKTIM1 [PKTIM]		16:41
[Row 12] PKCODE1 [PKCODE]		B - Late due to previous procedure

Variable	Old Value	New Value
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		30-May-2018
[Row 13] PKTIM1 [PKTIM]		17:10
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		30-May-2018
[Row 14] PKTIM1 [PKTIM]		17:40
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		30-May-2018
[Row 15] PKTIM1 [PKTIM]		18:10

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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Complete
System	04-Jun-2018 03:17 PM PDT (UTC-07:00)	Form marked as Not Complete
System	04-Jun-2018 03:17 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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".

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)	31-Jul-2018 02:24 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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 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	12-Jun-2018 10:19 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	12-Jun-2018 10:19 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 02:26 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Was Questionnaire performed? [QSPERF]	Yes

Use: [QSUSE]	2nd Use

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jun-2018 10:19 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	12-Jun-2018 10:19 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM 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)	31-Jul-2018 02:26 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	31-May-2018

AUDIT TRAIL

VISIT: Day 6
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:33 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		31-May-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

User	Date/Time	Change
System	05-Jun-2018 07:33 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:29 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Visit Date

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algopharm.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]	18:20

Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	31-May-2018
Time Taken: [VSTIM]	18:25
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	37
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	123
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure

Not done: [VSSTAT]	
Result: [VSORRES]	84
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	67
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	14
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Day 6
FORM: Vital Signs

Logged in User	[redacted] vinceandassociates.com [redacted]	
Date/Time	05-Jun-2018 07:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		18:20
VS1DAT [VSDAT]		31-May-2018
VSTIM [VSTIM]		18:25
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		37
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		123
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		84
[Row 3] VSORRESU [VSORRESU]		mmHg

Variable	Old Value	New Value
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		67
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		14
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	05-Jun-2018 07:35 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:43 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Vital Signs

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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: Chemistry Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	31-May-2018
Time of Collection: [LBTIM]	18:10
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	No
Row 1	
Test Name: [LBTEST]	Glucose
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS
Row 2	
Test Name: [LBTEST]	Lacitc Dehydrogenase (LD)

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

AUDIT TRAIL

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:36 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		31-May-2018
LBTIM5 [LBTIM]		18:10
LBNRIND5 [LBNRIND]		No
[Row 1] LBTEST [LBTEST]		Glucose
[Row 1] LBCLSIG5 [LBCLSIG]		NCS
[Row 2] LBTEST [LBTEST]		Lacitc Dehydrogenase (LD)
[Row 2] LBCLSIG5 [LBCLSIG]		NCS

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	05-Jun-2018 07:36 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:39 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	31-May-2018
Time of Collection: [LBTIM]	18:10
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	No

Row 1	
Test Name: [LBTEST]	WHITE BLOOD CELL
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	NCS
Row 2	
Test Name: [LBTEST]	LYMPHOCYTES ABSOLUTE
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) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:37 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
[Row 2] LBCLSIG6 [LBCLSIG]		NCS
Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:37 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		31-May-2018
LBTIM6 [LBTIM]		18:10

Variable	Old Value	New Value
LBNRIND6 [LBNRIND]		No
[Row 1] LBTEST6 [LBTEST]		WHITE BLOOD CELL
[Row 1] LBCLSIG6 [LBCLSIG]		NCS
[Row 2] LBTEST6 [LBTEST]		LYMPHOCYTES ABSOLUTE

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	05-Jun-2018 07:37 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 07:37 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 07:37 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:40 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 2] LBCLSIG6	Data Updated [05-Jun-2018 07:37 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	05-Jun-2018 07:37 AM	05-Jun-2018 07:37 AM
	Description			
	New: Evaluation is missing, please review **Old:** **By:** 05-Jun-2018 07:37 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)			

LOCKING HISTORY

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	31-May-2018
Time of Collection: [LBTIM]	06:48
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) [redacted] vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:38 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		31-May-2018
LBTIM7 [LBTIM]		06:48
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	05-Jun-2018 07:38 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:40 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Symptom Directed Physical Exam

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

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

AUDIT TRAIL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:38 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [PEYN]		No

FORM STATUS CHANGE LOG

VISIT: Day 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	05-Jun-2018 07:38 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:43 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

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

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	
Row 1	
Product: [EXPRDB]	
Session Start Time: [EXSRTTIMB]	

Session End Time: [EXENTMB]	

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [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 6
FORM: Part B - Uncontrolled Nicorette Dosing Log

User	Date/Time	Change
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [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	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Expected
System	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM 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	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	08-Jun-2018 06:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	31-May-2018
Session Start Time: [EXSTTIM]	09:10
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:10:00
Puff End: [EXPFEN]	09:10:04
Missed Puff: [EXMISPF]	No

If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	09:10:30
Puff End: [EXPFEN]	09:10:34
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:11:00
Puff End: [EXPFEN]	09:11:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:11:30
Puff End: [EXPFEN]	09:11:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:12:00
Puff End: [EXPFEN]	09:12:02
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:12:30
Puff End: [EXPFEN]	09:12:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:13:00
Puff End: [EXPFEN]	09:13:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:13:31
Puff End: [EXPFEN]	09:13:34
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:14:00
Puff End: [EXPFEN]	09:14:02
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 10	
Puff: [EXPFF]	Puff 10
Puff Begin: [EXPFBG]	09:14:30
Puff End: [EXPFEN]	09:14:34
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 6
FORM: Part B - Controlled VLN Dosing Log

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 08:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATVLN [EXDATVLN]		31-May-2018
EXSTTIM [EXSTTIM]		09:10
[Row 1] EXPFF [EXPFF]		Puff 1
[Row 1] EXPFBG [EXPFBG]		09:10:00
[Row 1] EXPFEN [EXPFEN]		09:10:04
[Row 1] EXMISPF [EXMISPF]		No
[Row 2] EXPFF [EXPFF]		Puff 2
[Row 2] EXPFBG [EXPFBG]		09:10:30
[Row 2] EXPFEN [EXPFEN]		09:10:34
[Row 2] EXMISPF [EXMISPF]		No
[Row 3] EXPFF [EXPFF]		Puff 3
[Row 3] EXPFBG [EXPFBG]		09:11:00
[Row 3] EXPFEN [EXPFEN]		09:11:04
[Row 3] EXMISPF [EXMISPF]		No
[Row 4] EXPFF [EXPFF]		Puff 4

Variable	Old Value	New Value
[Row 4] EXPFBG [EXPFBG]		09:11:30
[Row 4] EXPFEN [EXPFEN]		09:11:33
[Row 4] EXMISPF [EXMISPF]		No
[Row 5] EXPFF [EXPFF]		Puff 5
[Row 5] EXPFBG [EXPFBG]		09:12:00
[Row 5] EXPFEN [EXPFEN]		09:12:02
[Row 5] EXMISPF [EXMISPF]		No
[Row 6] EXPFF [EXPFF]		Puff 6
[Row 6] EXPFBG [EXPFBG]		09:12:30
[Row 6] EXPFEN [EXPFEN]		09:12:33
[Row 6] EXMISPF [EXMISPF]		No
[Row 7] EXPFF [EXPFF]		Puff 7
[Row 7] EXPFBG [EXPFBG]		09:13:00
[Row 7] EXPFEN [EXPFEN]		09:13:03
[Row 7] EXMISPF [EXMISPF]		No
[Row 8] EXPFF [EXPFF]		Puff 8
[Row 8] EXPFBG [EXPFBG]		09:13:31
[Row 8] EXPFEN [EXPFEN]		09:13:34
[Row 8] EXMISPF [EXMISPF]		No
[Row 9] EXPFF [EXPFF]		Puff 9
[Row 9] EXPFBG [EXPFBG]		09:14:00

Variable	Old Value	New Value
[Row 9] EXPFEN [EXPFEN]		09:14:02
[Row 9] EXMISPF [EXMISPF]		No
[Row 10] EXPFF [EXPFF]		Puff 10
[Row 10] EXPFBG [EXPFBG]		09:14:30
[Row 10] EXPFEN [EXPFEN]		09:14:34
[Row 10] EXMISPF [EXMISPF]		No
EXBEVB2 [EXBEVB2]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 08:40 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 08:12 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	
Date of Visit: [EXDATB]	31-May-2018
Session Start Time: [EXSRTTIM]	15:10
Session End Time: [EXENDTIM]	15:13
Row 1	
Inhalation Begin: [EXINHBG]	15:10:01
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:05
Time Unknown: [EXTIMUNK]	

Row 2	
Inhalation Begin: [EXINHBG]	15:10:28
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:30
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:10:37
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:38
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:10:50
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:52
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:11:02
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:04

Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:11:22
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:24
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:11:52
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:53
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:12:09
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:12:10
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:12:20
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	15:12:21
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:12:32
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:12:33
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	15:12:44
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:12:45
Time Unknown: [EXTIMUNK]	
Row 12	
Inhalation Begin: [EXINHBG]	15:12:58
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:00
Time Unknown: [EXTIMUNK]	
Row 13	
Inhalation Begin: [EXINHBG]	15:13:14

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:15
Time Unknown: [EXTIMUNK]	
Row 14	
Inhalation Begin: [EXINHBG]	15:13:29
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:30
Time Unknown: [EXTIMUNK]	
Row 15	
Inhalation Begin: [EXINHBG]	15:13:43
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:44
Time Unknown: [EXTIMUNK]	
Row 16	
Inhalation Begin: [EXINHBG]	15:13:48
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:49
Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	16

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 08:44 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX9DATB [EXDATB]		31-May-2018
EX9SRTTIM [EXSRTTIM]		15:10
EX9ENDTIM [EXENDTIM]		15:13
[Row 1] EX9INHBG [EXINHBG]		15:10:01
[Row 1] EX9INEN [EXINEN]		15:10:05
[Row 2] EX9INHBG [EXINHBG]		15:10:28
[Row 2] EX9INEN [EXINEN]		15:10:30
[Row 3] EX9INHBG [EXINHBG]		15:10:37
[Row 3] EX9INEN [EXINEN]		15:10:38
[Row 4] EX9INHBG [EXINHBG]		15:10:50
[Row 4] EX9INEN [EXINEN]		15:10:52
[Row 5] EX9INHBG [EXINHBG]		15:11:02
[Row 5] EX9INEN [EXINEN]		15:11:04
[Row 6] EX9INHBG [EXINHBG]		15:11:22

Variable	Old Value	New Value
[Row 6] EX9INEN [EXINEN]		15:11:24
[Row 7] EX9INHBG [EXINHBG]		15:11:52
[Row 7] EX9INEN [EXINEN]		15:11:53
[Row 8] EX9INHBG [EXINHBG]		15:12:09
[Row 8] EX9INEN [EXINEN]		15:12:10
[Row 9] EX9INHBG [EXINHBG]		15:12:20
[Row 9] EX9INEN [EXINEN]		15:12:21
[Row 10] EX9INHBG [EXINHBG]		15:12:32
[Row 10] EX9INEN [EXINEN]		15:12:33
[Row 11] EX9INHBG [EXINHBG]		15:12:44
[Row 11] EX9INEN [EXINEN]		15:12:45
[Row 12] EX9INHBG [EXINHBG]		15:12:58
[Row 12] EX9INEN [EXINEN]		15:13:00
[Row 13] EX9INHBG [EXINHBG]		15:13:14
[Row 13] EX9INEN [EXINEN]		15:13:15
[Row 14] EX9INHBG [EXINHBG]		15:13:29
[Row 14] EX9INEN [EXINEN]		15:13:30
[Row 15] EX9INHBG [EXINHBG]		15:13:43
[Row 15] EX9INEN [EXINEN]		15:13:44
[Row 16] EX9INHBG [EXINHBG]		15:13:48
[Row 16] EX9INEN [EXINEN]		15:13:49

Variable	Old Value	New Value
EX9BEVB [EXBEVB]		No
EX9INTOT [EXINTOT]		16

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 08:44 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 08:12 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:37 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	31-May-2018
Visit: [EGVIS]	Day 6
Row 1	
Time: [EGTIM]	18:18
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	65
PR Interval: [EGPR]	206
QRS Interval: [EGQRS]	92
QT Interval: [EGQT]	406
QTcB Interval: [EGQTCB]	423

QTcF: [EGQTCF]	417
Clinical Significance as per MD: [EGCLSIG]	ABNORMAL NCS
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) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT [EGDAT]		31-May-2018
EGVIS [EGVIS]		Day 6
[Row 1] EG1TIM [EGTIM]		18:18
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		65
[Row 1] EG1PR [EGPR]		206
[Row 1] EG1QRS [EGQRS]		92
[Row 1] EG1QT [EGQT]		406
[Row 1] EGQTCB [EGQTCB]		423
[Row 1] EG1QTCF [EGQTCF]		417
[Row 1] EG1CLSIG		ABNORMAL NCS

Variable	Old Value	New Value
[EGCLSIG]		

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	28-Jun-2018 09:00 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 07:40 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 07:40 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:42 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Day 6
FORM: ECG Test Results

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] EG1CLSIG	ABNORMAL NCS PER PRINCIPAL INVESTIGATOR [14-Jun-2018 09:32 AM by	05-Jun-2018 07:40 AM	28-Jun-2018 09:00 AM

ID	Variable	Responses/Reasons	Opened	Closed
		[redacted] vinceandassociates.com ([redacted] Response satisfies query [28-Jun-2018 09:00 AM by [redacted] vinceandassociates.com ([redacted] [redacted]		
	Description			
	New: Clinically Significant as per MD is Abnormal NCS. However, results are all within range. Please clarify. **Old:** **By:** 05-Jun-2018 07:40 AM [redacted] vinceandassociates.com ([redacted] [redacted]			

LOCKING HISTORY

VISIT: Day 6
FORM: ECG Test Results

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			[redacted] algopharm.com ([redacted] [redacted]	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	[redacted] vinceandassociates.com [redacted]	
Date/Time	05-Jun-2018 07:42 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 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	05-Jun-2018 07:42 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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**
[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]	31-Jul-2018 02:34 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:42 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 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	05-Jun-2018 07:42 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	31-Jul-2018 02:34 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Use: [QSUSE]	1st Use

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

AUDIT TRAIL

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

Logged in User	(b) (6) [redacted] vinceandassociates.com ([redacted]) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:43 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 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	05-Jun-2018 07:43 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:35 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	[redacted] vinceandassociates.com [redacted]	
Date/Time	05-Jun-2018 07:43 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 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	05-Jun-2018 07:43 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
[redacted] algopharm.com [redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com [redacted]	31-Jul-2018 02:35 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: End of Study

Visit Date [DSVDAT]	31-May-2018
Date of Completion or Discontinuation: [DSDAT]	31-May-2018
Date of Last Dose of Study Medication: [DSDOSDAT]	31-May-2018
Did the subject complete the study? [DSCOMYN]	Yes
If No, please mark the PRIMARY reason for discontinuation:	
Primary 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) (b) (6) (b) (6)
Date/Time	05-Jun-2018 07:44 AM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSVDAT1 [DSVDAT]		31-May-2018
DSDAT [DSDAT]		31-May-2018
DSDOSDT [DSDOSDAT]		31-May-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	05-Jun-2018 07:44 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:43 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: End of Study

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	31-May-2018
Time: [PKTIM]	09:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:12

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	09:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	10:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	10:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	C - Early Collection; please specify in Lab Note
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	12:10
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) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:52 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]		31-May-2018
[Row 1] PKTIM [PKTIM]		09:05
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		31-May-2018
[Row 2] PKTIM [PKTIM]		09:12
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		31-May-2018
[Row 3] PKTIM [PKTIM]		09:15
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		31-May-2018
[Row 4] PKTIM [PKTIM]		09:17
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT		31-May-2018

Variable	Old Value	New Value
[PKDAT]		
[Row 5] PKTIM [PKTIM]		09:20
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		31-May-2018
[Row 6] PKTIM [PKTIM]		09:22
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		31-May-2018
[Row 7] PKTIM [PKTIM]		09:25
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		31-May-2018
[Row 8] PKTIM [PKTIM]		09:30
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		31-May-2018
[Row 9] PKTIM [PKTIM]		09:41
[Row 9] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		31-May-2018
[Row 10] PKTIM [PKTIM]		09:55
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		31-May-2018
[Row 11] PKTIM [PKTIM]		10:11
[Row 11] PKCODE [PKCODE]		B - Late due to previous procedure

Variable	Old Value	New Value
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		31-May-2018
[Row 12] PKTIM [PKTIM]		10:41
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		31-May-2018
[Row 13] PKTIM [PKTIM]		11:10
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		31-May-2018
[Row 14] PKTIM [PKTIM]		11:35
[Row 14] PKCODE [PKCODE]		C - Early Collection; please specify in Lab Note
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		31-May-2018
[Row 15] PKTIM [PKTIM]		12:10

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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 07:52 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 07:52 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:38 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)	31-Jul-2018 02:31 PM 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]	31-May-2018

Time: [PKTIM]	15:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:22
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:29
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	31-May-2018

Time: [PKTIM]	15:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	15:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	16:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure

Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	16:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:18
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	18:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) (b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 04:49 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 9] PKCODE1 [PKCODE]		B - Late due to previous procedure

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	05-Jun-2018 07:56 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]		31-May-2018
[Row 1] PKTIM1 [PKTIM]		15:05
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		31-May-2018
[Row 2] PKTIM1 [PKTIM]		15:12
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		31-May-2018
[Row 3] PKTIM1 [PKTIM]		15:15
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		31-May-2018
[Row 4] PKTIM1 [PKTIM]		15:17
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		31-May-2018
[Row 5] PKTIM1 [PKTIM]		15:20
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		31-May-2018
[Row 6] PKTIM1		15:22

Variable	Old Value	New Value
[PKTIM]		
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		31-May-2018
[Row 7] PKTIM1 [PKTIM]		15:29
[Row 7] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		31-May-2018
[Row 8] PKTIM1 [PKTIM]		15:30
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		31-May-2018
[Row 9] PKTIM1 [PKTIM]		15:41
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		31-May-2018
[Row 10] PKTIM1 [PKTIM]		15:55
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		31-May-2018
[Row 11] PKTIM1 [PKTIM]		16:11
[Row 11] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		31-May-2018
[Row 12] PKTIM1 [PKTIM]		16:41
[Row 12] PKCODE1 [PKCODE]		B - Late due to previous procedure

Variable	Old Value	New Value
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		31-May-2018
[Row 13] PKTIM1 [PKTIM]		17:18
[Row 13] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		31-May-2018
[Row 14] PKTIM1 [PKTIM]		17:40
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		31-May-2018
[Row 15] PKTIM1 [PKTIM]		18:10

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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 07:56 AM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 07:56 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	12-Jun-2018 10:20 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 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	12-Jun-2018 10:20 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Use Product Again - VAS 1st use

User	**Date/Time**	**Status**
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	31-Jul-2018 02:35 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Use Product Again - VAS 1st use

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jun-2018 10:20 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 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	12-Jun-2018 10:20 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	05-Jun-2018 01:42 PM 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)	31-Jul-2018 02:35 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Early Term
FORM: Visit Date

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Visit Date

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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 PRIMARY reason for discontinuation:	
Primary 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	31-May-2018 09:38 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) algopharm.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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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)	05-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:38 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]	No
Row 1	
AE Identifier: [AESPID]	
Adverse Event Term: [AETERM]	
Is this an SAE? [AESER]	
Severity: [AESEV]	

Frequency: [AEFREQ]	
Action Taken with Study Treatment: [AEACN]	
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	
Did the AE result in withdrawal from study? [AEDIS]	
Relationship to Investigational Product: [AEREL]	
Was this AE a result of Study Medication error? [AETEAE]	
Outcome: [AEOUT]	
Onset Date: [AESTDAT]	
Onset Time: [AESTTIM]	
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	
End Date: [AEENDAT]	
End Time: [AEENTIM]	
Time Unknown: [AEENTMNK]	

AUDIT TRAIL

VISIT: All Visits
FORM: Adverse Events

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	06-Jun-2018 12:11 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
AEYN [AEYN]		No

FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Adverse Events

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 12:11 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 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)	31-Jul-2018 02:44 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: All Visits
FORM: Adverse Events

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

CLINICAL DATA

VISIT: All Visits
FORM: Concomitant Medications

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

Row 1	
CM Number: [CMNUM]	
Medication/Therapy/Procedure: [CMTRT]	
Indication: [CMINDC]	
If Other, please specify: [CMINDOT]	
Adverse Event #: [CMAENUM]	
Medical History #: [CMMHNUM]	
Strength: [CMDOSE]	
Unit: [CMDOSU]	
If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	
Form: [CMDOSFRM]	
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	

Unit: [CMTOTUN]	
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	
Start Time: [CMSTTIM]	
Time Unknown [CMSTTNK]	
End Date: [CMENDAT]	
End Time: [CMENTIM]	
Time Unknown [CMENTNK]	
Ongoing? [CMONGO]	

AUDIT TRAIL

VISIT: All Visits
FORM: Concomitant Medications

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	06-Jun-2018 12:11 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
CMYN [CMYN]		No

FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Concomitant Medications

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 12:11 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:38 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: All Visits
FORM: Concomitant Medications

User	**Date/Time**	**Status**
[redacted] gmail.com ([redacted]	25-Oct-2018 11:23 AM PDT (UTC-07:00)	Form marked as "Form Monitored".
[redacted] algopharm.com ([redacted]	11-Oct-2018 02:30 PM PDT (UTC-07:00)	Updated information (Form unmarked as "Form Monitored"). - ESignature
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	31-Jul-2018 02:45 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: All Visits
FORM: Concomitant Medications

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