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Site:	Site A
Group:	Group A
Medrio ID:	0037
Subject Identifier:	01-118
Status:	Completed
Timezone:	Pacific Standard Time
Study Name:	CEG-P9-153

SUBJECT INFORMATION HISTORY

Object	Date Time	User	Old Value	New Value
Subject Status	03-Jul-2018 10:34 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)	Enrolled	Completed
Subject ID	25-Jun-2018 08:21 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)		01-118
Medrio ID	25-Jun-2018 08:21 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)		37
Subject Status	25-Jun-2018 08:21 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)		Enrolled
Site	25-Jun-2018 08:21 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)		Site A
Group	25-Jun-2018 08:21 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)		Group A
ePRO Enabled	25-Jun-2018 08:21 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (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)

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

CLINICAL DATA

VISIT: Screening
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	18-Jun-2018

AUDIT TRAIL

VISIT: Screening
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:22 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		18-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:22 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Visit Date

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	01-Aug-2018 02:50 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]	18-Jun-2018
ICF Version: [DSVERS]	v3 ICF CEG-P9-153
ICF Version Date: [DSVDAT]	01-May-2018

AUDIT TRAIL

VISIT: Screening
FORM: ICF

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:23 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSYN [DSYN]		Yes
[Row 1] DSDATE [DSDAT]		18-Jun-2018
[Row 1] DSVERS [DSVERS]		v3 ICF CEG-P9-153
[Row 1] DSVDAT [DSVDAT]		01-May-2018

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: ICF

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:23 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ICF

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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	01-Aug-2018 02:08 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: ICF

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

CLINICAL DATA

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

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

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

AUDIT TRAIL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)
Date/Time	25-Jun-2018 08:24 AM PDT (UTC-07:00)

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:24 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

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

LOCKING HISTORY

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	18-Jun-2018
Date of Birth: [DMBRTHDAT]	(b) (6)
Age: [DMAGE]	49
Age Unit: [DMAGEU]	YEARS
Gender: [DMSEX]	M
Ethnicity: [DMETHNIC]	NOT HISPANIC OR LATINO
Race: [DMRACE]	WHITE
Other, Specify: [DMRCOT]	

AUDIT TRAIL

VISIT: Screening
FORM: Demographics

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:26 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DMDAT [DMDAT]		18-Jun-2018
DMBRTHDAT [DMBRTHDAT]		(b) (6)
DMAGE [DMAGE]		49
DMAGEU [DMAGEU]		YEARS

Variable	Old Value	New Value
DMSEX [DMSEX]		M
DMETHNIC [DMETHNIC]		NOT HISPANIC OR LATINO
DMRACE [DMRACE]		WHITE

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Demographics

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:26 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Demographics

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

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

CLINICAL DATA

VISIT: Screening
FORM: Medical History

Does the subject have any relevant medical or surgical history (including drug allergies)? [MHYN]	Yes
Date of Visit: [MHDAT]	18-Jun-2018
Row 1	
Medical History #: [MHNUM]	1
Body System Code: [MHSCAT]	Musculoskeletal
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	GENERALIZED BODY PAIN - WORK RELATED
Onset Date: [MHSTDAT]	UN-UNK-2008
Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	Yes
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 2	
Medical History #: [MHNUM]	2
Body System Code: [MHSCAT]	Musculoskeletal

If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	TEAR LEFT BICEP TENDON
Onset Date: [MHSTDAT]	UN-Oct-2015
Date Resolved: [MHENDAT]	UN-Dec-2015
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 3	
Medical History #: [MHNUM]	3
Body System Code: [MHSCAT]	Surgical
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	SURGICAL REPAIR LEFT SHOULDER
Onset Date: [MHSTDAT]	UN-Dec-2015
Date Resolved: [MHENDAT]	UN-Dec-2015
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 4	
Medical History #: [MHNUM]	4
Body System Code: [MHSCAT]	Musculoskeletal

If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	UNKNOWN INJURY LEFT KNEE
Onset Date: [MHSTDAT]	UN-UNK-1992
Date Resolved: [MHENDAT]	UN-UNK-1992
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 5	
Medical History #: [MHNUM]	5
Body System Code: [MHSCAT]	Surgical
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	ARTHOSCOPY LEFT KNEE
Onset Date: [MHSTDAT]	UN-UNK-1992
Date Resolved: [MHENDAT]	UN-UNK-1992
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 6	
Medical History #: [MHNUM]	6
Body System Code: [MHSCAT]	Musculoskeletal

If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	LOW BACK PAIN
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]	Yes

AUDIT TRAIL

VISIT: Screening
FORM: Medical History

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:47 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
MHYN [MHYN]		Yes
MHDAT [MHDAT]		18-Jun-2018
[Row 1] MHNUM [MHNUM]		1
[Row 1] MHSCAT [MHSCAT]		Musculoskeletal
[Row 1] MHCAT [MHSCAT]		GENERALIZED BODY PAIN - WORK RELATED

Variable	Old Value	New Value
[Row 1] MHSTDAT [MHSTDAT]		UN-UNK-2008
[Row 1] MHONGO [MHONGO]		Yes
[Row 1] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 2] MHNUM [MHNUM]		2
[Row 2] MHSCAT [MHSCAT]		Musculoskeletal
[Row 2] MHCAT [MHSCAT]		TEAR LEFT BICEP TENDON
[Row 2] MHSTDAT [MHSTDAT]		UN-Oct-2015
[Row 2] MHENDAT [MHENDAT]		UN-Dec-2015
[Row 2] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 3] MHNUM [MHNUM]		3
[Row 3] MHSCAT [MHSCAT]		Surgical
[Row 3] MHCAT [MHSCAT]		SURGICAL REPAIR LEFT SHOULDER
[Row 3] MHSTDAT [MHSTDAT]		UN-Dec-2015
[Row 3] MHENDAT [MHENDAT]		UN-Dec-2015
[Row 3] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 4] MHNUM [MHNUM]		4
[Row 4] MHSCAT [MHSCAT]		Musculoskeletal
[Row 4] MHCAT [MHSCAT]		UNKNOWN INJURY LEFT KNEE
[Row 4] MHSTDAT [MHSTDAT]		UN-UNK-1992
[Row 4] MHENDAT [MHENDAT]		UN-UNK-1992
[Row 4] MHCLSIG [MHCLSIG]		Not Clinically Sigficant

Variable	Old Value	New Value
[Row 5] MHNUM [MHNUM]		5
[Row 5] MHSCAT [MHSCAT]		Surgical
[Row 5] MHCAT [MHSCAT]		ARTHOSCOPY LEFT KNEE
[Row 5] MHSTDAT [MHSTDAT]		UN-UNK-1992
[Row 5] MHENDAT [MHENDAT]		UN-UNK-1992
[Row 5] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 6] MHNUM [MHNUM]		6
[Row 6] MHSCAT [MHSCAT]		Musculoskeletal
[Row 6] MHCAT [MHSCAT]		LOW BACK PAIN
[Row 6] MHSTDAT [MHSTDAT]		UN-UNK-2000
[Row 6] MHONGO [MHONGO]		Yes
[Row 6] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
MHSMK [MHSMK]		Yes
MHRECUSE [MHRECUSE]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Medical History

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:47 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Medical History

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

LOCKING HISTORY

VISIT: Screening
FORM: Medical History

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	18-Jun-2018
Completion Time: [PETIM]	11:39
Row 1	
Body System Examined: [PETEST]	GENERAL APPEARANCE

Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 2	
Body System Examined: [PETEST]	HEENT
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 3	
Body System Examined: [PETEST]	NECK/THYROID
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 4	
Body System Examined: [PETEST]	CARDIOVASCULAR
Not done: [PESTAT]	

If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 5	
Body System Examined: [PETEST]	RESPIRATORY
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 6	
Body System Examined: [PETEST]	GASTROINTESTINAL
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 7	
Body System Examined: [PETEST]	NEUROLOGICAL
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	

Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 8	
Body System Examined: [PETEST]	MUSCULOSKELETAL/EXTREMITIES
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 9	
Body System Examined: [PETEST]	SKIN
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 10	
Body System Examined: [PETEST]	OTHER
Not done: [PESTAT]	Yes
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	

Abnormal Findings: [PEDESC]	

AUDIT TRAIL

VISIT: Screening
FORM: Complete Physical Examination

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:48 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN [PEYN]		Yes
PEDAT [PEDAT]		18-Jun-2018
PETIM [PETIM]		11:39
[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		NORMAL

Variable	Old Value	New Value
[PEORRES]		
[Row 7] PETEST [PETEST]		NEUROLOGICAL
[Row 7] PEORRES [PEORRES]		NORMAL
[Row 8] PETEST [PETEST]		MUSCULOSKELETAL/EXTREMITIES
[Row 8] PEORRES [PEORRES]		NORMAL
[Row 9] PETEST [PETEST]		SKIN
[Row 9] PEORRES [PEORRES]		NORMAL
[Row 10] PETEST [PETEST]		OTHER
[Row 10] PESTAT [PESTAT]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Complete Physical Examination

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:48 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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

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

LOCKING HISTORY

VISIT: Screening
FORM: Complete Physical Examination

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algo pharm.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]	18-Jun-2018
Height: [VSHGT]	171.0
Weight: [VSWGT]	72.2
BMI: [VSBMI]	24.7

AUDIT TRAIL

VISIT: Screening
FORM: Height, Weight and BMI

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:48 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSYN [VSYN]		Yes

Variable	Old Value	New Value
VSDAT [VSDAT]		18-Jun-2018
VSHGT [VSHGT]		171.0
VSWGT [VSWGT]		72.2
VSBMI [VSBMI]		24.7

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Height, Weight and BMI

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:48 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Height, Weight and BMI

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

CLINICAL DATA

VISIT: Screening
FORM: Serology Lab Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	18-Jun-2018
Time of Collection: [LBTIM]	11:05
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes
Row 1	
Test Name: [LBTEST]	
Clinical Significance as per MD: (Please record an AE for Clinically Significant results) [LBCLSIG]	

AUDIT TRAIL

VISIT: Screening
FORM: Serology Lab Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)
Date/Time	25-Jun-2018 08:49 AM 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]	11:07	11:05
Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN [LBYN]		Yes
LBDAT [LBDAT]		18-Jun-2018
LBTIM [LBTIM]		11:07
LBNRIND [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serology Lab Evaluation

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:49 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Serology Lab Evaluation

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

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

LOCKING HISTORY

VISIT: Screening
FORM: Serology Lab Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Serum Pregnancy Test

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serum Pregnancy Test

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Screening
FORM: Serum Pregnancy Test

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

CLINICAL DATA

VISIT: Screening
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	10:55
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	18-Jun-2018
Time Taken: [VSTIM]	11:00
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.4
Unit: [VSORRESU]	C

MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	125
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]	72
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: Screening
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:50 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		10:55
VS1DAT [VSDAT]		18-Jun-2018
VSTIM [VSTIM]		11:00
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.4
[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]		125
[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
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		72
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		15
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:50 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Vital Signs

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

LOCKING HISTORY

VISIT: Screening
FORM: Vital Signs

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	18-Jun-2018
Time of Collection: [LBTIM]	11:07
Time Unknown: [LBTMNK]	

Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:51 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		18-Jun-2018
LBTIM3 [LBTIM]		11:07
LBNRIND3 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:51 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

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

LOCKING HISTORY

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	18-Jun-2018
Time of Collection: [LBTIM]	11:07
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:51 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN4 [LBYN]		Yes
LBDAT4 [LBDAT]		18-Jun-2018
LBTIM4 [LBTIM]		11:07
LBNRIND4 [LBNRIND]		No
[Row 1] LBTEST5 [LBTEST]		Cotinine
[Row 1] LBCLSIG4 [LBCLSIG]		NCS

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Cotinine Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:51 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Cotinine Evaluation

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

LOCKING HISTORY

VISIT: Screening
FORM: Cotinine Evaluation

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	18-Jun-2018
Time of Collection: [LBTIM]	11:05
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	No

Row 1	
Test Name: [LBTEST]	Creatine Phosphokinase (CK)
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) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:52 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		18-Jun-2018
LBTIM5 [LBTIM]		11:05
LBNRIND5 [LBNRIND]		No
[Row 1] LBTEST [LBTEST]		Creatine Phosphokinase (CK)
[Row 1] LBCLSIG5 [LBCLSIG]		NCS

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:52 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

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

LOCKING HISTORY

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	18-Jun-2018
Time of Collection: [LBTIM]	11:05
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:53 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		18-Jun-2018
LBTIM6 [LBTIM]		11:05
LBNRIND6 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Hematology Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:53 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

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

LOCKING HISTORY

VISIT: Screening
FORM: Hematology Laboratory Evaluation

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	18-Jun-2018
Time of Collection: [LBTIM]	11:07
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:53 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		18-Jun-2018
LBTIM7 [LBTIM]		11:07
LBNRIND7 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:53 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

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

LOCKING HISTORY

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Endocrinology Evaluation

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

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Endocrinology Evaluation

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Screening
FORM: Endocrinology Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: ECG Test Results

Was the ECG performed? [EGYN]	Yes
Date: [EGDAT]	18-Jun-2018
Visit: [EGVIS]	Screening

Row 1	
Time: [EGTIM]	10:52
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	60
PR Interval: [EGPR]	146
QRS Interval: [EGQRS]	109
QT Interval: [EGQT]	426
QTcB Interval: [EGQTCB]	426
QTcF: [EGQTCF]	426
Clinical Significance as per MD: [EGCLSIG]	ABNORMAL NCS
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Screening
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 08:58 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes

Variable	Old Value	New Value
EG1DAT [EGDAT]		18-Jun-2018
EGVIS [EGVIS]		Screening
[Row 1] EG1TIM [EGTIM]		10:52
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		60
[Row 1] EG1PR [EGPR]		146
[Row 1] EG1QRS [EGQRS]		109
[Row 1] EG1QT [EGQT]		426
[Row 1] EGQTCB [EGQTCB]		426
[Row 1] EG1QTCF [EGQTCF]		426
[Row 1] EG1CLSIG [EGCLSIG]		ABNORMAL NCS

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	28-Jun-2018 08:59 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:58 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:58 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: ECG Test Results

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] EG1CLSIG	ABNORMAL NCS PER PRINCIPAL INVESTIGATOR [25-Jun-2018 12:19 PM by (b) (6) vinceandassociates.com (b) (6) Response satisfies query [28-Jun-2018 08:59 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	25-Jun-2018 08:58 AM	28-Jun-2018 08:59 AM
	Description			
	New: Clinically Significant as per MD is Abnormal NCS. However, results are all within range. Please clarify. **Old:** **By:** 25-Jun-2018 08:58 AM (b) (6) vinceandassociates.com (b) (6) (b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: ECG Test Results

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

CLINICAL DATA

VISIT: Screening
FORM: Female Contraceptive Method

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

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

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Female Contraceptive Method

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Screening
FORM: Female Contraceptive Method

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

CLINICAL DATA

VISIT: Screening
FORM: Tobacco Use

Row 1	
Type of tobacco used? [SUTRT]	Cigarette(s)
Frequency: [SUFRQ]	Current
Start Date: [SUSTDAT]	UN-UNK-1997
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	

Daily Use: [SUDYUS]	25
Row 2	
Type of tobacco used? [SUTRT]	Cigar(s)
Frequency: [SUFRQ]	Never
Start Date: [SUSTDAT]	
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	
Daily Use: [SUDYUS]	
Row 3	
Type of tobacco used? [SUTRT]	Cigarillo(s)
Frequency: [SUFRQ]	Never
Start Date: [SUSTDAT]	
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	

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

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

Daily Use: [SUDYUS]	

AUDIT TRAIL

VISIT: Screening
FORM: Tobacco Use

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 11:17 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-1997
[Row 1] SUDYUS1 [SUDYUS]		25
[Row 2] SUTRT1 [SUTRT]		Cigar(s)
[Row 2] SUFRQ1 [SUFRQ]		Never
[Row 3] SUTRT1 [SUTRT]		Cigarillo(s)
[Row 3] SUFRQ1 [SUFRQ]		Never
[Row 4] SUTRT1 [SUTRT]		Chewing Tobacco
[Row 4] SUFRQ1 [SUFRQ]		Never
[Row 5] SUTRT1 [SUTRT]		Pipe(s)
[Row 5] SUFRQ1 [SUFRQ]		Never
[Row 6] SUTRT1 [SUTRT]		Nicotine Product(s): (patch, gum, etc)
[Row 6] SUFRQ1 [SUFRQ]		Never
[Row 7] SUTRT1 [SUTRT]		Electronic Cigarette(s)/E-Vapors

Variable	Old Value	New Value
[Row 7] SUFRQ1 [SUFRQ]		Never

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Tobacco Use

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	16-Jul-2018 09:21 AM PDT (UTC-07:00)	Form marked as Complete
System	11-Jul-2018 11:17 AM PDT (UTC-07:00)	Form marked as Not Complete
System	11-Jul-2018 11:17 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Tobacco Use

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] SUYRUS1	NOT APPLICABLE [11-Jul-2018 11:18 AM by (b) (6) vinceandass	11-Jul-2018 11:17 AM	16-Jul-2018 09:21 AM

ID	Variable	Responses/Reasons	Opened	Closed
		ociates.com ([b] (6) [redacted] Response satisfies query [16-Jul-2018 09:21 AM by [b] (6) vinceandassociates.com ([b] (6) [b] (6)		
	Description			
	New: Yearly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:17 AM [b] (6) vinceandassociates.com ([b] (6) [redacted]			
	[Row 1] SUWKUS1	NOT APPLICABLE [11-Jul-2018 11:18 AM by [b] (6) vinceandassociates.com ([b] (6) [redacted] Response satisfies query [16-Jul-2018 09:21 AM by [b] (6) vinceandassociates.com ([b] (6) [b] (6)	11-Jul-2018 11:17 AM	16-Jul-2018 09:21 AM
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 11-Jul-2018 11:17 AM [b] (6) vinceandassociates.com ([b] (6) [redacted]			
	[Row 1] SUMONUS1	NOT APPLICABLE [11-Jul-2018 11:18 AM by [b] (6) vinceandassociates.com ([b] (6) [redacted] Response satisfies query [16-Jul-2018 09:21 AM by [b] (6) vinceandassociates.com ([b] (6) [b] (6)	11-Jul-2018 11:17 AM	16-Jul-2018 09:21 AM
	Description			
	New: Monthly Use is missing, please review			

ID	Variable	Responses/Reasons	Opened	Closed
	Old: **By:** 11-Jul-2018 11:17 AM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: Tobacco Use

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

CLINICAL DATA

VISIT: Day -1
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	22-Jun-2018

AUDIT TRAIL

VISIT: Day -1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 09:23 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		22-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 09:23 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Visit Date

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

LOCKING HISTORY

VISIT: Day -1
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day -1
FORM: Urine Pregnancy Test

Was Urine Pregnancy Test performed? [LBHCGYN]	

Date of collection: [LBDAT]	
Time of Collection: [LBTIM]	
Time Unknown: [LBTMNK]	

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Urine Pregnancy Test

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Day -1
FORM: Urine Pregnancy Test

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

CLINICAL DATA

VISIT: Day -1
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	07:32
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	22-Jun-2018

Time Taken: [VSTIM]	07:37
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]	118
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	78

Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	80
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	14
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Day -1
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 09:26 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		07:32
VS1DAT [VSDAT]		22-Jun-2018
VSTIM [VSTIM]		07:37
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.6
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		118
[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

Variable	Old Value	New Value
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		80
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		14
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Vital Signs

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

FORM APPROVAL

VISIT: Day -1
FORM: Vital Signs

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

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

LOCKING HISTORY

VISIT: Day -1
FORM: Vital Signs

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

CLINICAL DATA

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

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	22-Jun-2018
Time of Collection: [LBTIM]	07:23
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 09:28 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		22-Jun-2018
LBTIM3 [LBTIM]		07:23
LBNRIND3 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

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

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

FORM APPROVAL

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

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

AUDIT TRAIL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

Logged in User	[redacted] vinceandassociates.com [redacted]	
Date/Time	25-Jun-2018 09:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [PEYN]		No

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Symptom Directed Physical Exam

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 09:35 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

LOCKING HISTORY

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

VISIT: Day 1
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 09:36 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		23-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Visit Date

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

User	Date/Time	Change
System	25-Jun-2018 09:36 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Visit Date

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

LOCKING HISTORY

VISIT: Day 1
FORM: Visit Date

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

CLINICAL DATA

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

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

Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:50
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:58
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:59
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:09
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:38
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:48

Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:49
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:56
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:42
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]	11:52
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:58

Row 7	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:12
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:19
Row 8	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:20
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:26
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]	13:12

Row 10	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:13
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:20
Row 11	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:39
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:45
Row 12	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:46
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:49

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 09:10 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		23-Jun-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM [EXTIM]		09:50
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		09:58
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1
[Row 2] EXTIM [EXTIM]		09:59
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		10:09
[Row 3] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		10:38
[Row 3] EXCIGRET [EXCIGRET]		1
[Row 3] EXTIMRET [EXTIMRET]		10:48
[Row 4] EXPRDT		Combustible Cigarette

Variable	Old Value	New Value
[EXPRDT]		
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		10:49
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		10:56
[Row 5] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD [EXDSPD]		1
[Row 5] EXTIM [EXTIM]		11:42
[Row 5] EXCIGRET [EXCIGRET]		1
[Row 5] EXTIMRET [EXTIMRET]		11:51
[Row 6] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD [EXDSPD]		1
[Row 6] EXTIM [EXTIM]		11:52
[Row 6] EXCIGRET [EXCIGRET]		1
[Row 6] EXTIMRET [EXTIMRET]		11:58
[Row 7] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD [EXDSPD]		1
[Row 7] EXTIM [EXTIM]		12:12
[Row 7] EXCIGRET [EXCIGRET]		1
[Row 7] EXTIMRET [EXTIMRET]		12:19
[Row 8] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 8] EXDSPD [EXDSPD]		1

Variable	Old Value	New Value
[Row 8] EXTIM [EXTIM]		12:20
[Row 8] EXCIGRET [EXCIGRET]		1
[Row 8] EXTIMRET [EXTIMRET]		12:26
[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]		13:12
[Row 10] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 10] EXDSPD [EXDSPD]		1
[Row 10] EXTIM [EXTIM]		13:13
[Row 10] EXCIGRET [EXCIGRET]		1
[Row 10] EXTIMRET [EXTIMRET]		13:20
[Row 11] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 11] EXDSPD [EXDSPD]		1
[Row 11] EXTIM [EXTIM]		13:39
[Row 11] EXCIGRET [EXCIGRET]		1
[Row 11] EXTIMRET [EXTIMRET]		13:45
[Row 12] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 12] EXDSPD [EXDSPD]		1
[Row 12] EXTIM [EXTIM]		13:46

Variable	Old Value	New Value
[Row 12] EXCIGRET [EXCIGRET]		1
[Row 12] EXTIMRET [EXTIMRET]		13:49

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	26-Jun-2018 09:10 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:49 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	02-Aug-2018 09:01 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 1
FORM: Randomization

Date of Randomization: [DSRDAT]	23-Jun-2018
Randomization Number: [DSNUM]	1040
Sequence Group [DSRNGRP]	BCA

AUDIT TRAIL

VISIT: Day 1
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	25-Jun-2018 08:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSRNDAT		23-Jun-2018

Variable	Old Value	New Value
[DSRDAT]		
DSRNUM [DSNUM]		1040
DSRNGRP [DSRNGRP]		BCA

FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Randomization

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 08:49 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Randomization

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

LOCKING HISTORY

VISIT: Day 1
FORM: Randomization

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

CLINICAL DATA

VISIT: Day 1
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 1
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 09:38 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Use Product Again - VAS

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 09:38 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Use Product Again - VAS

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

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

LOCKING HISTORY

VISIT: Day 1
FORM: Use Product Again - VAS

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	24-Jun-2018

AUDIT TRAIL

VISIT: Day 2
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 09:36 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		24-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	25-Jun-2018 09:36 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 2
FORM: Visit Date

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

CLINICAL DATA

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

AD LIB USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG	

Date of Visit: [EXDAT]	
Row 1	
Product Used: [EXPRDT]	
Number Dispensed: [EXDSPD]	
Time Dispensed: [EXTIM]	
Number of Butts Returned: [EXCIGRET]	
Time Returned: [EXTIMRET]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

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

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

CLINICAL DATA

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

AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG	
Date of Visit: [EXDAT]	24-Jun-2018
Row 1	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:50
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	09:56
Row 2	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:36
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	13:48

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 08:38 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT2 [EXDAT]		24-Jun-2018
[Row 1] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXDSPD2 [EXDSPD]		1
[Row 1] EXTIM2 [EXTIM]		09:50
[Row 1] EXNICRET [EXNICRET]		1
[Row 1] EXTIMRET2 [EXTIMRET]		09:56
[Row 2] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 2] EXDSPD2 [EXDSPD]		1
[Row 2] EXTIM2 [EXTIM]		13:36
[Row 2] EXNICRET [EXNICRET]		1
[Row 2] EXTIMRET2 [EXTIMRET]		13:48

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	26-Jun-2018 08:38 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:49 AM PDT (UTC-07:00)	Form marked as Not Complete

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 2
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 2
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	25-Jun-2018 09:37 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	25-Jun-2018 09:37 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
FORM: Use Product Again - VAS

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

LOCKING HISTORY

VISIT: Day 2
FORM: Use Product Again - VAS

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

CLINICAL DATA

VISIT: Day 3
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 3
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	26-Jun-2018 08:27 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		25-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Day 3
FORM: Visit Date

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
FORM: Visit Date

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

LOCKING HISTORY

VISIT: Day 3
FORM: Visit Date

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

CLINICAL DATA

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

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 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) 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 - VLN Dosing Log

AD LIB VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG	
Date of Visit: [EXDAT]	25-Jun-2018

Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:50
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:54
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:56
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:01
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]	10:27

Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:28
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:33
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:05
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:12
Row 6	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:13
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:19

Row 7	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:58
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:02
Row 8	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:42
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:50
Row 9	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:51
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:56

Row 10	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:25
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:30
Row 11	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:39
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:43

AUDIT TRAIL

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

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

Variable	Old Value	New Value
[Row 1] EXDSPD1 [EXDSPD]		1
[Row 1] EXTIM1 [EXTIM]		09:50
[Row 1] EXCIGRET1 [EXCIGRET]		1
[Row 1] EXTIMRET1 [EXTIMRET]		09:54
[Row 2] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD1 [EXDSPD]		1
[Row 2] EXTIM1 [EXTIM]		09:56
[Row 2] EXCIGRET1 [EXCIGRET]		1
[Row 2] EXTIMRET1 [EXTIMRET]		10:01
[Row 3] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD1 [EXDSPD]		1
[Row 3] EXTIM1 [EXTIM]		10:19
[Row 3] EXCIGRET1 [EXCIGRET]		1
[Row 3] EXTIMRET1 [EXTIMRET]		10:27
[Row 4] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD1 [EXDSPD]		1
[Row 4] EXTIM1 [EXTIM]		10:28
[Row 4] EXCIGRET1 [EXCIGRET]		1
[Row 4] EXTIMRET1 [EXTIMRET]		10:33
[Row 5] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD1 [EXDSPD]		1

Variable	Old Value	New Value
[Row 5] EXTIM1 [EXTIM]		11:05
[Row 5] EXCIGRET1 [EXCIGRET]		1
[Row 5] EXTIMRET1 [EXTIMRET]		11:12
[Row 6] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD1 [EXDSPD]		1
[Row 6] EXTIM1 [EXTIM]		11:13
[Row 6] EXCIGRET1 [EXCIGRET]		1
[Row 6] EXTIMRET1 [EXTIMRET]		11:19
[Row 7] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD1 [EXDSPD]		1
[Row 7] EXTIM1 [EXTIM]		11:58
[Row 7] EXCIGRET1 [EXCIGRET]		1
[Row 7] EXTIMRET1 [EXTIMRET]		12:02
[Row 8] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 8] EXDSPD1 [EXDSPD]		1
[Row 8] EXTIM1 [EXTIM]		12:42
[Row 8] EXCIGRET1 [EXCIGRET]		1
[Row 8] EXTIMRET1 [EXTIMRET]		12:50
[Row 9] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 9] EXDSPD1 [EXDSPD]		1
[Row 9] EXTIM1 [EXTIM]		12:51

Variable	Old Value	New Value
[Row 9] EXCIGRET1 [EXCIGRET]		1
[Row 9] EXTIMRET1 [EXTIMRET]		12:56
[Row 10] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 10] EXDSPD1 [EXDSPD]		1
[Row 10] EXTIM1 [EXTIM]		13:25
[Row 10] EXCIGRET1 [EXCIGRET]		1
[Row 10] EXTIMRET1 [EXTIMRET]		13:30
[Row 11] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 11] EXDSPD1 [EXDSPD]		1
[Row 11] EXTIM1 [EXTIM]		13:39
[Row 11] EXCIGRET1 [EXCIGRET]		1
[Row 11] EXTIMRET1 [EXTIMRET]		13:43

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	26-Jun-2018 09:26 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:49 AM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 3
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 3
FORM: Use Product Again - VAS

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	26-Jun-2018 08:27 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 3
FORM: Use Product Again - VAS

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

FORM APPROVAL

VISIT: Day 3
FORM: Use Product Again - VAS

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

LOCKING HISTORY

VISIT: Day 3
FORM: Use Product Again - VAS

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

CLINICAL DATA

VISIT: Day 4
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 4
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 12:48 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		26-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	27-Jun-2018 12:48 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 4
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day 4
FORM: Randomization

Date of Randomization: [DSRDAT]	26-Jun-2018
Randomization Number: [DSNUM]	2039
Sequence Group [DSRNGRP]	CAB

AUDIT TRAIL

VISIT: Day 4
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	27-Jun-2018 12:34 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		26-Jun-2018
DSRNUM [DSNUM]		2039
DSRNGRP [DSRNGRP]		CAB

FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Randomization

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	27-Jun-2018 12:34 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
FORM: Randomization

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

LOCKING HISTORY

VISIT: Day 4
FORM: Randomization

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

CLINICAL DATA

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

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	26-Jun-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	09:50
Session End Time: [EXENTMB]	10:00
Did the subject consume any beverages during controlled product use?: [EXBEV]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)
Date/Time	27-Jun-2018 01:16 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT [EXNICDAT]		26-Jun-2018
[Row 1] EXPRDB [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB [EXSRTTIMB]		09:50
[Row 1] EXENTMB [EXENTMB]		10:00
EXBEV [EXBEV]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	27-Jun-2018 01:16 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:34 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 09:05 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-2

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]	

AUDIT TRAIL

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-2

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 01:17 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
EXNICDAT [EXNICDAT]	26-Jun-2018	
[Row 1] EXPRDB [EXPRDB]	Nicorette Original Flavor Gum (4 mg)	
[Row 1] EXSRTTIMB [EXSRTTIMB]	15:50	
[Row 1] EXENTMB [EXENTMB]	16:00	
EXBEV [EXBEV]	No	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 01:16 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT [EXNICDAT]		26-Jun-2018
[Row 1] EXPRDB [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB [EXSRTTIMB]		15:50
[Row 1] EXENTMB [EXENTMB]		16:00
EXBEV [EXBEV]		No

FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-2

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	27-Jun-2018 01:17 PM PDT (UTC-07:00)	Form marked as Not Expected
System	27-Jun-2018 01:17 PM PDT (UTC-07:00)	Form marked as Not Complete
System	27-Jun-2018 01:16 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FIELD STATUSES

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-2

Variable	Row Number	User	Date/Time	Field status
EXPRDB	1	(b) (6) vinceandassociates.com (b) (6)	27-Jun-2018 01:17 PM PDT (UTC-07:00)	The status was set to Cleared
EXSRTTIMB	1	(b) (6) vinceandassociates.com (b) (6)	27-Jun-2018 01:17 PM PDT (UTC-07:00)	The status was set to Cleared
EXENTMB	1	(b) (6) vinceandassociates.com (b) (6)	27-Jun-2018 01:17 PM PDT (UTC-07:00)	The status was set to Cleared
EXNICDAT		(b) (6) vinceandassociates.com (b) (6)	27-Jun-2018 01:17 PM PDT (UTC-07:00)	The status was set to Cleared
EXBEV		(b) (6) vinceandassociates.com (b) (6)	27-Jun-2018 01:17 PM PDT (UTC-07:00)	The status was set to Cleared

LOCKING HISTORY

VISIT: Day 4
FORM: Part B - Controlled Nicorette Dosing Log-2

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

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

CLINICAL DATA

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

UNCONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	26-Jun-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	15:50
Session End Time: [EXENTMB]	16:00
Did the subject consume any beverages during controlled product use?: [EXBEV]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	27-Jun-2018 01:17 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT2 [EXNICDAT]		26-Jun-2018
[Row 1] EXPRDB2 [EXPRDB]		Nicorette Original Flavor Gum (4 mg)

Variable	Old Value	New Value
[Row 1] EXSRTTIMB2 [EXSRTTIMB]		15:50
[Row 1] EXENTMB2 [EXENTMB]		16:00
EXBEV2 [EXBEV]		No

FORM STATUS CHANGE LOG

VISIT: Day 4
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	27-Jun-2018 01:17 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:34 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	
Date of Visit: [EXDATB]	
Session Start Time: [EXSRTTIM]	
Session End Time: [EXENDTIM]	
Row 1	
Inhalation Begin: [EXINHBG]	
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	
Time Unknown: [EXTIMUNK]	
Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	

Session Total Inhalations: [EXINTOT]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	
Session Start Time: [EXSTTIM]	
Row 1	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	
Date of Visit: [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	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF [QSPERF]		Yes

Variable	Old Value	New Value
QSUSE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:35 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF1 [QSPERF]		Yes
QSUSE_1 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:35 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	28-Jun-2018 09:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF_1 [QSPERF]		Yes
QSUSE_2 [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:35 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF2 [QSPERF]		Yes
QSUSE2 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:35 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:56

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	09:57
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:06
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	10:53

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	11:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	11:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	12:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	12:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:32 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

Variable	Old Value	New Value
[Row 1] PKDAT [PKDAT]		26-Jun-2018
[Row 1] PKTIM [PKTIM]		09:45
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		26-Jun-2018
[Row 2] PKTIM [PKTIM]		09:52
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		26-Jun-2018
[Row 3] PKTIM [PKTIM]		09:56
[Row 3] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		26-Jun-2018
[Row 4] PKTIM [PKTIM]		09:57
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		26-Jun-2018
[Row 5] PKTIM [PKTIM]		10:00
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		26-Jun-2018
[Row 6] PKTIM [PKTIM]		10:02
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		26-Jun-2018
[Row 7] PKTIM [PKTIM]		10:06

Variable	Old Value	New Value
[Row 7] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		26-Jun-2018
[Row 8] PKTIM [PKTIM]		10:10
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		26-Jun-2018
[Row 9] PKTIM [PKTIM]		10:20
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		26-Jun-2018
[Row 10] PKTIM [PKTIM]		10:35
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		26-Jun-2018
[Row 11] PKTIM [PKTIM]		10:53
[Row 11] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		26-Jun-2018
[Row 12] PKTIM [PKTIM]		11:21
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		26-Jun-2018
[Row 13] PKTIM [PKTIM]		11:50

Variable	Old Value	New Value
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		26-Jun-2018
[Row 14] PKTIM [PKTIM]		12:20
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		26-Jun-2018
[Row 15] PKTIM [PKTIM]		12:50

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:32 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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 - PK Blood Sampling

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:52

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	15:58
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:06
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:35

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	16:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	17:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	17:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	18:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	26-Jun-2018
Time: [PKTIM]	18:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:34 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		26-Jun-2018
[Row 1] PKTIM1 [PKTIM]		15:45
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		26-Jun-2018
[Row 2] PKTIM1 [PKTIM]		15:52
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		26-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:55
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		26-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:58
[Row 4] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 5] PKTPT1 [PKTPT]		10 minute

Variable	Old Value	New Value
[Row 5] PKDAT1 [PKDAT]		26-Jun-2018
[Row 5] PKTIM1 [PKTIM]		16:00
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		26-Jun-2018
[Row 6] PKTIM1 [PKTIM]		16:02
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		26-Jun-2018
[Row 7] PKTIM1 [PKTIM]		16:06
[Row 7] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		26-Jun-2018
[Row 8] PKTIM1 [PKTIM]		16:10
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		26-Jun-2018
[Row 9] PKTIM1 [PKTIM]		16:20
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		26-Jun-2018
[Row 10] PKTIM1 [PKTIM]		16:35
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		26-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:50

Variable	Old Value	New Value
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		26-Jun-2018
[Row 12] PKTIM1 [PKTIM]		17:20
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		26-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:50
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		26-Jun-2018
[Row 14] PKTIM1 [PKTIM]		18:20
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		26-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:50

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:34 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	28-Jun-2018 09:34 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:34 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:35 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 5
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 5
FORM: Visit Date

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	28-Jun-2018 09:36 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		27-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:36 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 5
FORM: Visit Date

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

LOCKING HISTORY

VISIT: Day 5
FORM: Visit Date

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Not Expected

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

CLINICAL DATA

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

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

Row 1	
Product: [EXPRDB]	
Session Start Time: [EXSRTTIMB]	
Session End Time: [EXENTMB]	

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	
Date of Visit: [EXDATB]	
Session Start Time: [EXSRTTIM]	
Session End Time: [EXENDTIM]	
Row 1	
Inhalation Begin: [EXINHBG]	
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	
Time Unknown: [EXTIMUNK]	
Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	

Session Total Inhalations: [EXINTOT]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	
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	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	27-Jun-2018

Session Start Time: [EXSTTIM]	09:50
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:50:00
Puff End: [EXPFEN]	09:50:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	09:50:30
Puff End: [EXPFEN]	09:50:34
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:51:00
Puff End: [EXPFEN]	09:51:03
Missed Puff: [EXMISPF]	No

If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:51:30
Puff End: [EXPFEN]	09:51:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:52:00
Puff End: [EXPFEN]	09:52:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:52:30
Puff End: [EXPFEN]	09:52:35
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:53:00
Puff End: [EXPFEN]	09:53:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:53:30
Puff End: [EXPFEN]	09:53:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:54:00
Puff End: [EXPFEN]	09:54:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 01:57 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATVLN [EXDATVLN]		27-Jun-2018
EXSTTIM [EXSTTIM]		09:50
[Row 1] EXPFF [EXPFF]		Puff 1
[Row 1] EXPFBG [EXPFBG]		09:50:00
[Row 1] EXPFEN [EXPFEN]		09:50:03
[Row 1] EXMISPF [EXMISPF]		No
[Row 2] EXPFF [EXPFF]		Puff 2
[Row 2] EXPFBG		09:50:30

Variable	Old Value	New Value
[EXPFBG]		
[Row 2] EXPFEN [EXPFEN]		09:50:34
[Row 2] EXMISPF [EXMISPF]		No
[Row 3] EXPFF [EXPFF]		Puff 3
[Row 3] EXPFBG [EXPFBG]		09:51:00
[Row 3] EXPFEN [EXPFEN]		09:51:03
[Row 3] EXMISPF [EXMISPF]		No
[Row 4] EXPFF [EXPFF]		Puff 4
[Row 4] EXPFBG [EXPFBG]		09:51:30
[Row 4] EXPFEN [EXPFEN]		09:51:33
[Row 4] EXMISPF [EXMISPF]		No
[Row 5] EXPFF [EXPFF]		Puff 5
[Row 5] EXPFBG [EXPFBG]		09:52:00
[Row 5] EXPFEN [EXPFEN]		09:52:03
[Row 5] EXMISPF [EXMISPF]		No
[Row 6] EXPFF [EXPFF]		Puff 6
[Row 6] EXPFBG [EXPFBG]		09:52:30
[Row 6] EXPFEN [EXPFEN]		09:52:35
[Row 6] EXMISPF [EXMISPF]		No
[Row 7] EXPFF [EXPFF]		Puff 7
[Row 7] EXPFBG [EXPFBG]		09:53:00
[Row 7] EXPFEN [EXPFEN]		09:53:03

Variable	Old Value	New Value
[Row 7] EXMISPF [EXMISPF]		No
[Row 8] EXPFF [EXPFF]		Puff 8
[Row 8] EXPFBG [EXPFBG]		09:53:30
[Row 8] EXPFEN [EXPFEN]		09:53:33
[Row 8] EXMISPF [EXMISPF]		No
[Row 9] EXPFF [EXPFF]		Puff 9
[Row 9] EXPFBG [EXPFBG]		09:54:00
[Row 9] EXPFEN [EXPFEN]		09:54:03
[Row 9] EXMISPF [EXMISPF]		No
[Row 10] EXMISPF [EXMISPF]		Yes
[Row 10] EXCOM [EXCOM]		CIGARETTE ENDED
EXBEVB2 [EXBEVB2]		No

FORM STATUS CHANGE LOG

VISIT: Day 5
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	28-Jun-2018 01:57 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:34 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 09:06 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) 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 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]	27-Jun-2018
Session Start Time: [EXSRTTIM]	15:50
Session End Time: [EXENDTIM]	15:54

Row 1	
Inhalation Begin: [EXINHBG]	15:50:01
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:50:02
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:50:04
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:50:07
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:50:29
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:50:32
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:50:52
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:50:54

Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:51:14
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:51:17
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:51:43
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:51:44
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:52:02
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:52:05
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:52:55
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	15:52:57
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:53:13
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:53:15
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:53:45
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:53:46
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	15:54:15
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:54:17
Time Unknown: [EXTIMUNK]	
Row 12	
Inhalation Begin: [EXINHBG]	15:54:28

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:54:31
Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	12

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 02:00 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX9DATB [EXDATB]		27-Jun-2018
EX9SRTTIM [EXSRTTIM]		15:50
EX9ENDTIM [EXENDTIM]		15:54
[Row 1] EX9INHBG [EXINHBG]		15:50:01
[Row 1] EX9INEN [EXINEN]		15:50:02
[Row 2] EX9INHBG [EXINHBG]		15:50:04
[Row 2] EX9INEN [EXINEN]		15:50:07
[Row 3] EX9INHBG [EXINHBG]		15:50:29
[Row 3] EX9INEN [EXINEN]		15:50:32
[Row 4] EX9INHBG		15:50:52

Variable	Old Value	New Value
[EXINHBG]		
[Row 4] EX9INEN [EXINEN]		15:50:54
[Row 5] EX9INHBG [EXINHBG]		15:51:14
[Row 5] EX9INEN [EXINEN]		15:51:17
[Row 6] EX9INHBG [EXINHBG]		15:51:43
[Row 6] EX9INEN [EXINEN]		15:51:44
[Row 7] EX9INHBG [EXINHBG]		15:52:02
[Row 7] EX9INEN [EXINEN]		15:52:05
[Row 8] EX9INHBG [EXINHBG]		15:52:55
[Row 8] EX9INEN [EXINEN]		15:52:57
[Row 9] EX9INHBG [EXINHBG]		15:53:13
[Row 9] EX9INEN [EXINEN]		15:53:15
[Row 10] EX9INHBG [EXINHBG]		15:53:45
[Row 10] EX9INEN [EXINEN]		15:53:46
[Row 11] EX9INHBG [EXINHBG]		15:54:15
[Row 11] EX9INEN [EXINEN]		15:54:17
[Row 12] EX9INHBG [EXINHBG]		15:54:28
[Row 12] EX9INEN [EXINEN]		15:54:31
EX9BEVB [EXBEVB]		No
EX9INTOT [EXINTOT]		12

FORM STATUS CHANGE LOG

VISIT: Day 5
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	28-Jun-2018 02:00 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:34 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF [QSPERF]		Yes
QSUSE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:40 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	28-Jun-2018 09:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF1 [QSPERF]		Yes
QSUSE_1 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:40 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF_1 [QSPERF]		Yes
QSUSE_2 [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:40 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 02:30 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)	
Date/Time	28-Jun-2018 09:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF2 [QSPERF]		Yes
QSUSE2 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:40 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:30 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:45

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	09:57
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:20

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	10:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	11:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	11:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	12:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	12:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:38 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE1 [PKUSE]		1st Use (Morning Draw)
[Row 1] PKTPT [PKTPT]		Predose
[Row 1] PKDAT [PKDAT]		27-Jun-2018
[Row 1] PKTIM [PKTIM]		09:45
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		27-Jun-2018
[Row 2] PKTIM		09:52

Variable	Old Value	New Value
[PKTIM]		
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		27-Jun-2018
[Row 3] PKTIM [PKTIM]		09:55
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		27-Jun-2018
[Row 4] PKTIM [PKTIM]		09:57
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		27-Jun-2018
[Row 5] PKTIM [PKTIM]		10:00
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		27-Jun-2018
[Row 6] PKTIM [PKTIM]		10:02
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		27-Jun-2018
[Row 7] PKTIM [PKTIM]		10:05
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		27-Jun-2018
[Row 8] PKTIM [PKTIM]		10:10
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		27-Jun-2018
[Row 9] PKTIM [PKTIM]		10:20

Variable	Old Value	New Value
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		27-Jun-2018
[Row 10] PKTIM [PKTIM]		10:35
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		27-Jun-2018
[Row 11] PKTIM [PKTIM]		10:50
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		27-Jun-2018
[Row 12] PKTIM [PKTIM]		11:21
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		27-Jun-2018
[Row 13] PKTIM [PKTIM]		11:50
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		27-Jun-2018
[Row 14] PKTIM [PKTIM]		12:20
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		27-Jun-2018
[Row 15] PKTIM [PKTIM]		12:50

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:38 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	15:57
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	16:50

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	17:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	17:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute

Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	18:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	27-Jun-2018
Time: [PKTIM]	18:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:40 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

Variable	Old Value	New Value
[Row 1] PKDAT1 [PKDAT]		27-Jun-2018
[Row 1] PKTIM1 [PKTIM]		15:45
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		27-Jun-2018
[Row 2] PKTIM1 [PKTIM]		15:52
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		27-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:55
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		27-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:57
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		27-Jun-2018
[Row 5] PKTIM1 [PKTIM]		16:00
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		27-Jun-2018
[Row 6] PKTIM1 [PKTIM]		16:02
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		27-Jun-2018
[Row 7] PKTIM1 [PKTIM]		16:05
[Row 8] PKTPT1 [PKTPT]		20 minute

Variable	Old Value	New Value
[Row 8] PKDAT1 [PKDAT]		27-Jun-2018
[Row 8] PKTIM1 [PKTIM]		16:10
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		27-Jun-2018
[Row 9] PKTIM1 [PKTIM]		16:20
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		27-Jun-2018
[Row 10] PKTIM1 [PKTIM]		16:35
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		27-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:50
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		27-Jun-2018
[Row 12] PKTIM1 [PKTIM]		17:20
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		27-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:50
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		27-Jun-2018
[Row 14] PKTIM1 [PKTIM]		18:20
[Row 15] PKTPT1 [PKTPT]		180 minute

Variable	Old Value	New Value
[Row 15] PKDAT1 [PKDAT]		27-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:50

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:40 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:41 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:41 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 09:41 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 09:41 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: Visit Date

Visit Done? [SVYN]	Yes

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

AUDIT TRAIL

VISIT: Day 6
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 09:32 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		28-Jun-2018

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Visit Date

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 09:32 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day 6
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	19:00
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	28-Jun-2018
Time Taken: [VSTIM]	19:05
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	37.1
Unit: [VSORRESU]	C

MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	118
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	79
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	73
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

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

AUDIT TRAIL

VISIT: Day 6
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 12:57 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		19:00
VS1DAT [VSDAT]		28-Jun-2018
VSTIM [VSTIM]		19:05
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		37.1
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		118
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[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]		73
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		16
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:57 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Vital Signs

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	28-Jun-2018
Time of Collection: [LBTIM]	18:50
Time Unknown: [LBTMNK]	

Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 10:16 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		28-Jun-2018
LBTIM5 [LBTIM]		18:50
LBNRIND5 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	02-Jul-2018 10:16 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	28-Jun-2018
Time of Collection: [LBTIM]	18:50
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 10:17 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		28-Jun-2018
LBTIM6 [LBTIM]		18:50
LBNRIND6 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	02-Jul-2018 10:17 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	28-Jun-2018
Time of Collection: [LBTIM]	06:28
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	02-Jul-2018 10:17 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		28-Jun-2018
LBTIM7 [LBTIM]		06:28
LBNRIND7 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	02-Jul-2018 10:17 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Symptom Directed Physical Exam

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

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

AUDIT TRAIL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	29-Jun-2018 12:58 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [PEYN]		No

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Symptom Directed Physical Exam

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:58 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 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	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [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	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	28-Jun-2018
Session Start Time: [EXSTTIM]	09:50

Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:50:01
Puff End: [EXPFEN]	09:50:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	09:50:30
Puff End: [EXPFEN]	09:50:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:51:00
Puff End: [EXPFEN]	09:51:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:51:30
Puff End: [EXPFEN]	09:51:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:52:00
Puff End: [EXPFEN]	09:52:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:52:30
Puff End: [EXPFEN]	09:52:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:53:01
Puff End: [EXPFEN]	09:53:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:53:30
Puff End: [EXPFEN]	09:53:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:54:00
Puff End: [EXPFEN]	09:54:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 10	
Puff: [EXPFF]	Puff 10
Puff Begin: [EXPFBG]	09:54:30
Puff End: [EXPFEN]	09:54:33
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 6
FORM: Part B - Controlled Usual Brand Dosing Log

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	28-Jun-2018 02:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX8DATVLN [EXDATVLN]		28-Jun-2018
EX8STTIM [EXSTTIM]		09:50
[Row 1] EX8PFF [EXPFF]		Puff 1
[Row 1] EX8PFBG [EXPFBG]		09:50:01
[Row 1] EX8PFEN [EXPFEN]		09:50:04
[Row 1] EX8MISPF [EXMISPF]		No
[Row 2] EX8PFF [EXPFF]		Puff 2
[Row 2] EX8PFBG		09:50:30

Variable	Old Value	New Value
[EXPFBG]		
[Row 2] EX8PFEN [EXPFEN]		09:50:33
[Row 2] EX8MISPF [EXMISPF]		No
[Row 3] EX8PFF [EXPFF]		Puff 3
[Row 3] EX8PFBG [EXPFBG]		09:51:00
[Row 3] EX8PFEN [EXPFEN]		09:51:03
[Row 3] EX8MISPF [EXMISPF]		No
[Row 4] EX8PFF [EXPFF]		Puff 4
[Row 4] EX8PFBG [EXPFBG]		09:51:30
[Row 4] EX8PFEN [EXPFEN]		09:51:33
[Row 4] EX8MISPF [EXMISPF]		No
[Row 5] EX8PFF [EXPFF]		Puff 5
[Row 5] EX8PFBG [EXPFBG]		09:52:00
[Row 5] EX8PFEN [EXPFEN]		09:52:03
[Row 5] EX8MISPF [EXMISPF]		No
[Row 6] EX8PFF [EXPFF]		Puff 6
[Row 6] EX8PFBG [EXPFBG]		09:52:30
[Row 6] EX8PFEN [EXPFEN]		09:52:33
[Row 6] EX8MISPF [EXMISPF]		No
[Row 7] EX8PFF [EXPFF]		Puff 7
[Row 7] EX8PFBG [EXPFBG]		09:53:01
[Row 7] EX8PFEN [EXPFEN]		09:53:04

Variable	Old Value	New Value
[Row 7] EX8MISPF [EXMISPF]		No
[Row 8] EX8PFF [EXPFF]		Puff 8
[Row 8] EX8PFBG [EXPFBG]		09:53:30
[Row 8] EX8PFEN [EXPFEN]		09:53:33
[Row 8] EX8MISPF [EXMISPF]		No
[Row 9] EX8PFF [EXPFF]		Puff 9
[Row 9] EX8PFBG [EXPFBG]		09:54:00
[Row 9] EX8PFEN [EXPFEN]		09:54:03
[Row 9] EX8MISPF [EXMISPF]		No
[Row 10] EX8PFF [EXPFF]		Puff 10
[Row 10] EX8PFBG [EXPFBG]		09:54:30
[Row 10] EX8PFEN [EXPFEN]		09:54:33
[Row 10] EX8MISPF [EXMISPF]		No
EX8BEVB [EXBEVB]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 02:03 PM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:34 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	02-Aug-2018 09:08 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

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) 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 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]	28-Jun-2018
Session Start Time: [EXSRTTIM]	15:50

Session End Time: [EXENDTIM]	15:56
Row 1	
Inhalation Begin: [EXINHBG]	15:50:01
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:50:05
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:50:28
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:50:30
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:50:41
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:50:45
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:51:04
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	15:51:08
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:51:27
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:51:30
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:51:56
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:52:00
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:52:27
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:52:30
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:52:52

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:52:55
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	15:53:23
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:53:25
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	15:54:02
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:54:05
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	15:54:24
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:54:27
Time Unknown: [EXTIMUNK]	

Row 12	
Inhalation Begin: [EXINHBG]	15:54:53
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:54:56
Time Unknown: [EXTIMUNK]	
Row 13	
Inhalation Begin: [EXINHBG]	15:55:10
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:55:13
Time Unknown: [EXTIMUNK]	
Row 14	
Inhalation Begin: [EXINHBG]	15:55:33
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:55:35
Time Unknown: [EXTIMUNK]	
Row 15	
Inhalation Begin: [EXINHBG]	15:56:05
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:56:06

Time Unknown: [EXTIMUNK]	
Row 16	
Inhalation Begin: [EXINHBG]	15:56:15
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:56:18
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 Usual Brand Dosing Log

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 09:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATB [EXDATB]		28-Jun-2018
EXSRTTIM [EXSRTTIM]		15:50
EXENDTIM [EXENDTIM]		15:56
[Row 1] EXINHBG [EXINHBG]		15:50:01
[Row 1] EXINEN [EXINEN]		15:50:05
[Row 2] EXINHBG [EXINHBG]		15:50:28

Variable	Old Value	New Value
[Row 2] EXINEN [EXINEN]		15:50:30
[Row 3] EXINHBG [EXINHBG]		15:50:41
[Row 3] EXINEN [EXINEN]		15:50:45
[Row 4] EXINHBG [EXINHBG]		15:51:04
[Row 4] EXINEN [EXINEN]		15:51:08
[Row 5] EXINHBG [EXINHBG]		15:51:27
[Row 5] EXINEN [EXINEN]		15:51:30
[Row 6] EXINHBG [EXINHBG]		15:51:56
[Row 6] EXINEN [EXINEN]		15:52:00
[Row 7] EXINHBG [EXINHBG]		15:52:27
[Row 7] EXINEN [EXINEN]		15:52:30
[Row 8] EXINHBG [EXINHBG]		15:52:52
[Row 8] EXINEN [EXINEN]		15:52:55
[Row 9] EXINHBG [EXINHBG]		15:53:23
[Row 9] EXINEN [EXINEN]		15:53:25
[Row 10] EXINHBG [EXINHBG]		15:54:02
[Row 10] EXINEN [EXINEN]		15:54:05
[Row 11] EXINHBG [EXINHBG]		15:54:24
[Row 11] EXINEN [EXINEN]		15:54:27
[Row 12] EXINHBG [EXINHBG]		15:54:53
[Row 12] EXINEN [EXINEN]		15:54:56

Variable	Old Value	New Value
[Row 13] EXINHBG [EXINHBG]		15:55:10
[Row 13] EXINEN [EXINEN]		15:55:13
[Row 14] EXINHBG [EXINHBG]		15:55:33
[Row 14] EXINEN [EXINEN]		15:55:35
[Row 15] EXINHBG [EXINHBG]		15:56:05
[Row 15] EXINEN [EXINEN]		15:56:06
[Row 16] EXINHBG [EXINHBG]		15:56:15
[Row 16] EXINEN [EXINEN]		15:56:18
EXBEVB [EXBEVB]		No
EXINTOT [EXINTOT]		16

FORM STATUS CHANGE LOG

VISIT: Day 6
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	29-Jun-2018 09:35 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 12:34 PM PDT (UTC-07:00)	Form marked as Not Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 09:08 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Row 1	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	
If yes, provide reason: [EXCOM]	

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	
Date of Visit: [EXDATB]	
Session Start Time: [EXSRTTIM]	
Session End Time: [EXENDTIM]	

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: ECG Test Results

Was the ECG performed? [EGYN]	Yes
Date: [EGDAT]	28-Jun-2018
Visit: [EGVIS]	Day 6
Row 1	
Time: [EGTIM]	18:58
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	57
PR Interval: [EGPR]	155
QRS Interval: [EGQRS]	100

QT Interval: [EGQT]	394
QTcB Interval: [EGQTCB]	384
QTcF: [EGQTCF]	387
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)	
Date/Time	29-Jun-2018 12:56 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT [EGDAT]		28-Jun-2018
EGVIS [EGVIS]		Day 6
[Row 1] EG1TIM [EGTIM]		18:58
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		57
[Row 1] EG1PR [EGPR]		155
[Row 1] EG1QRS [EGQRS]		100
[Row 1] EG1QT [EGQT]		394
[Row 1] EGQTCB		384

Variable	Old Value	New Value
[EGQTCB]		
[Row 1] EG1QTCF [EGQTCF]		387
[Row 1] EG1CLSIG [EGCLSIG]		ABNORMAL NCS

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	17-Jul-2018 02:26 PM PDT (UTC-07:00)	Form marked as Complete
System	29-Jun-2018 12:56 PM PDT (UTC-07:00)	Form marked as Not Complete
System	29-Jun-2018 12:56 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: ECG Test Results

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 02:36 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 [29-Jun-2018 12:57 PM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [17-Jul-2018 02:26 PM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	29-Jun-2018 12:56 PM	17-Jul-2018 02:26 PM
	Description			
	New: Clinically Significant as per MD is Abnormal NCS. However, results are all within range. Please clarify. **Old:** **By:** 29-Jun-2018 12:56 PM (b) (6) vinceandassociates.com ((b) (6) (b) (6)			

LOCKING HISTORY

VISIT: Day 6
FORM: ECG Test Results

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

CLINICAL DATA

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

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

Use: [QSUSE]	1st Use

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	03-Jul-2018 10:25 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	03-Jul-2018 10:25 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	29-Jun-2018 12:59 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF1 [QSPERF]		Yes
QSUSE_1 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:59 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	03-Jul-2018 10:26 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	03-Jul-2018 10:26 AM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 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	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 12:59 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF2 [QSPERF]		Yes
QSUSE2 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:59 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: End of Study

Visit Date [DSVDAT]	28-Jun-2018
Date of Completion or Discontinuation: [DSDAT]	28-Jun-2018
Date of Last Dose of Study Medication: [DSDOSDAT]	28-Jun-2018
Did the subject complete the study? [DSCOMYN]	Yes
If No, please mark the (b) (6) reason for discontinuation:	

(b) (6) reason for study discontinuation: [DSDECOD]	
If Other, please specify: [DSTERM]	
Additional Comments: [DSCOM]	

AUDIT TRAIL

VISIT: Day 6
FORM: End of Study

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	29-Jun-2018 12:58 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSVDAT1 [DSVDAT]		28-Jun-2018
DSDAT [DSDAT]		28-Jun-2018
DSDOSDT [DSDOSDAT]		28-Jun-2018
DSCOMYN [DSCOMYN]		Yes

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: End of Study

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:58 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: End of Study

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 02:36 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]	28-Jun-2018
Time: [PKTIM]	09:45

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	Yes
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	09:57
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	Yes
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:21

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	10:53
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	11:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	11:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	12:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	A - Late due to difficult collection
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	12:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 12:52 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE1 [PKUSE]		1st Use (Morning Draw)
[Row 1] PKTPT [PKTPT]		Predose
[Row 1] PKDAT [PKDAT]		28-Jun-2018
[Row 1] PKTIM [PKTIM]		09:45
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		28-Jun-2018
[Row 2] PKTIM		09:52

Variable	Old Value	New Value
[PKTIM]		
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKSTAT [PKSTAT]		Yes
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		28-Jun-2018
[Row 4] PKTIM [PKTIM]		09:57
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		28-Jun-2018
[Row 5] PKTIM [PKTIM]		10:00
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKSTAT [PKSTAT]		Yes
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		28-Jun-2018
[Row 7] PKTIM [PKTIM]		10:05
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		28-Jun-2018
[Row 8] PKTIM [PKTIM]		10:10
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		28-Jun-2018
[Row 9] PKTIM [PKTIM]		10:21
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		28-Jun-2018

Variable	Old Value	New Value
[Row 10] PKTIM [PKTIM]		10:35
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		28-Jun-2018
[Row 11] PKTIM [PKTIM]		10:53
[Row 11] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		28-Jun-2018
[Row 12] PKTIM [PKTIM]		11:21
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		28-Jun-2018
[Row 13] PKTIM [PKTIM]		11:50
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		28-Jun-2018
[Row 14] PKTIM [PKTIM]		12:21
[Row 14] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		28-Jun-2018
[Row 15] PKTIM [PKTIM]		12:50

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:52 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 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)	07-Aug-2018 02:36 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]	28-Jun-2018
Time: [PKTIM]	15:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:52
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	15:57
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:21
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:36
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	16:50

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	17:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	17:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute

Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	18:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	28-Jun-2018
Time: [PKTIM]	18:50
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	29-Jun-2018 12:55 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

Variable	Old Value	New Value
[Row 1] PKDAT1 [PKDAT]		28-Jun-2018
[Row 1] PKTIM1 [PKTIM]		15:45
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		28-Jun-2018
[Row 2] PKTIM1 [PKTIM]		15:52
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		28-Jun-2018
[Row 3] PKTIM1 [PKTIM]		15:55
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		28-Jun-2018
[Row 4] PKTIM1 [PKTIM]		15:57
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		28-Jun-2018
[Row 5] PKTIM1 [PKTIM]		16:00
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		28-Jun-2018
[Row 6] PKTIM1 [PKTIM]		16:02
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		28-Jun-2018
[Row 7] PKTIM1 [PKTIM]		16:05
[Row 8] PKTPT1 [PKTPT]		20 minute

Variable	Old Value	New Value
[Row 8] PKDAT1 [PKDAT]		28-Jun-2018
[Row 8] PKTIM1 [PKTIM]		16:10
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		28-Jun-2018
[Row 9] PKTIM1 [PKTIM]		16:21
[Row 9] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		28-Jun-2018
[Row 10] PKTIM1 [PKTIM]		16:36
[Row 10] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		28-Jun-2018
[Row 11] PKTIM1 [PKTIM]		16:50
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		28-Jun-2018
[Row 12] PKTIM1 [PKTIM]		17:20
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		28-Jun-2018
[Row 13] PKTIM1 [PKTIM]		17:50
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		28-Jun-2018

Variable	Old Value	New Value
[Row 14] PKTIM1 [PKTIM]		18:20
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		28-Jun-2018
[Row 15] PKTIM1 [PKTIM]		18:50

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:55 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 02:36 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	29-Jun-2018 12:59 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:59 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	29-Jun-2018 12:59 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	29-Jun-2018 12:59 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Early Term
FORM: Visit Date

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Visit Date

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Visit Date

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

CLINICAL DATA

VISIT: Early Term
FORM: Vital Signs

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

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Vital Signs

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

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

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

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

CLINICAL DATA

VISIT: Early Term
FORM: Hematology Laboratory Evaluation

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

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Hematology Laboratory Evaluation

User	Date/Time	Change
(b) (6) vinceandassociates.com ((b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Hematology Laboratory Evaluation

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

CLINICAL DATA

VISIT: Early Term
FORM: Urinalysis Laboratory Evaluation

Visit: [LBVIS]	
Was the laboratory evaluation performed? [LBYN]	
Date of collection: [LBDAT]	
Time of Collection: [LBTIM]	

Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Urinalysis Laboratory Evaluation

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Urinalysis Laboratory Evaluation

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

CLINICAL DATA

VISIT: Early Term
FORM: Symptom Directed Physical Exam

Visit: [PEVIS]	
Was physical examination performed? [PEYN]	

Examination Date: [PEDAT]	
Completion Time: [PTIM]	
ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM	

Row 1	
Body System Examined: [PETEST]	
Not done: [PESTAT]	
Examination Results: [PEORRES]	
Abnormal Findings: [PECLSIG]	

If Other, please specify: [PEOTHSP]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Symptom Directed Physical Exam

User	Date/Time	Change
(b) (6) vinceandassociates.com ((b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

VISIT: Early Term
FORM: ECG Test Results

Was the ECG performed? [EGYN]	
Date: [EGDAT]	
Visit: [EGVIS]	

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: ECG Test Results

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: ECG Test Results

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

CLINICAL DATA

VISIT: Early Term
FORM: End of Study

Visit Date [DSVDAT]	
Date of Completion or Discontinuation: [DSDAT]	
Date of Last Dose of Study Medication: [DSDOSDAT]	
Did the subject complete the study? [DSCOMYN]	
If No, please mark the (b) (6) reason for discontinuation:	
(b) (6) reason for study discontinuation: [DSDECOD]	
If Other, please specify: [DSTERM]	

Additional Comments: [DSCOM]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: End of Study

User	Date/Time	Change
(b) (6) vinceandassociates.com ((b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: End of Study

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

CLINICAL DATA

VISIT: Early Term
FORM: 1st Use - PK Blood Sampling

Use: [PKUSE]	
Row 1	
Timepoint: [PKTPT]	
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: 1st Use - PK Blood Sampling

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: 1st Use - PK Blood Sampling

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

CLINICAL DATA

VISIT: Early Term
FORM: 2nd Use - PK Blood Sampling

Use: [PKUSE]	
Row 1	
Timepoint: [PKTPT]	
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: 2nd Use - PK Blood Sampling

User	Date/Time	Change
(b) (6) vinceandassociates.com ((b) (6)	29-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	25-Jun-2018 08:21 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: All Visits
FORM: Adverse Events

Were any Adverse Events experienced? [AEYN]	Yes
Row 1	
AE Identifier: [AESPID]	1
Adverse Event Term: [AETERM]	HEADACHE
Is this an SAE? [AESER]	No

Severity: [AESEV]	MODERATE
Frequency: [AEFREQ]	Continuous
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	Yes
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Unlikely Related
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	23-Jun-2018
Onset Time: [AESTTIM]	17:20
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	23-Jun-2018
End Time: [AEENTIM]	19:35
Time Unknown: [AEENTMNK]	

AUDIT TRAIL

VISIT: All Visits
FORM: Adverse Events

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 02:06 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
AEYN [AEYN]		Yes
[Row 1] AECMNM_deleted [AECMNM_deleted]		3
[Row 1] AESPID [AESPID]		1
[Row 1] AETERM [AETERM]		HEADACHE
[Row 1] AESER [AESER]		No
[Row 1] AESEV [AESEV]		MODERATE
[Row 1] AEFREQ [AEFREQ]		Continuous
[Row 1] AEACN [AEACN]		No Action Taken
[Row 1] AECONTRT [AECONTRT]		Yes
[Row 1] AEDIS [AEDIS]		No
[Row 1] AEREL [AEREL]		Unlikely Related
[Row 1] AETEAE [AETEAE]		No
[Row 1] AEOUT [AEOUT]		Resolved
[Row 1] AESTDAT [AESTDAT]		23-Jun-2018
[Row 1] AESTTIM [AESTTIM]		17:20
[Row 1] AEONGO [AEONGO]		No
[Row 1] AEENDAT		23-Jun-2018

Variable	Old Value	New Value
[AEENDAT]		
[Row 1] AEENTIM [AEENTIM]		19:35

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	27-Jun-2018 02:06 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: All Visits
FORM: Adverse Events

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 02:36 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]	Yes

Row 1	
CM Number: [CMNUM]	1
Medication/Therapy/Procedure: [CMTRT]	ALEVE
Indication: [CMINDC]	Medical History
If Other, please specify: [CMINDOT]	
Adverse Event #: [CMAENUM]	
Medical History #: [CMMHNUM]	1
Strength: [CMDOSE]	220
Unit: [CMDOSU]	mg
If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	1
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	220

Unit: [CMTOTUN]	mg
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	ONCE
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	15-Jun-2018
Start Time: [CMSTTIM]	
Time Unknown [CMSTTNK]	Yes
End Date: [CMENDAT]	15-Jun-2018
End Time: [CMENTIM]	
Time Unknown [CMENTNK]	Yes
Ongoing? [CMONGO]	
Row 2	
CM Number: [CMNUM]	2
Medication/Therapy/Procedure: [CMTRT]	IBUPROFEN
Indication: [CMINDC]	Medical History
If Other, please specify: [CMINDOT]	

Adverse Event #: [CMAENUM]	
Medical History #: [CMMHNUM]	1
Strength: [CMDOSE]	250
Unit: [CMDOSU]	mg
If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	2
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	500
Unit: [CMTOTUN]	mg
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	ONCE
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	12-Jun-2018
Start Time: [CMSTTIM]	
Time Unknown [CMSTTNK]	Yes

End Date: [CMENDAT]	12-Jun-2018
End Time: [CMENTIM]	
Time Unknown [CMENTNK]	Yes
Ongoing? [CMONGO]	
Row 3	
CM Number: [CMNUM]	3
Medication/Therapy/Procedure: [CMTRT]	ACETAMINOPHEN
Indication: [CMINDC]	Adverse Event
If Other, please specify: [CMINDOT]	
Adverse Event #: [CMAENUM]	1
Medical History #: [CMMHNUM]	
Strength: [CMDOSE]	325
Unit: [CMDOSU]	mg
If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	2
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	650

Unit: [CMTOTUN]	mg
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	ONCE
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	23-Jun-2018
Start Time: [CMSTTIM]	17:35
Time Unknown [CMSTTNK]	
End Date: [CMENDAT]	23-Jun-2018
End Time: [CMENTIM]	17:35
Time Unknown [CMENTNK]	
Ongoing? [CMONGO]	

AUDIT TRAIL

VISIT: All Visits
FORM: Concomitant Medications

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6)	
Date/Time	06-Aug-2018 10:34 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 1] CMTOTUN [CMTOTUN]		mg
[Row 2] CMTOTUN [CMTOTUN]		mg
Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6)	
Date/Time	06-Aug-2018 10:33 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 1] CMDOSU [CMDOSU]		mg
[Row 2] CMDOSU [CMDOSU]		mg
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	27-Jun-2018 02:16 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
CMYN [CMYN]		Yes
[Row 1] CMNUM [CMNUM]		1
[Row 1] CMTRT [CMTRT]		ALEVE
[Row 1] CMINDC [CMINDC]		Medical History
[Row 1] CMMHNUM [CMMHNUM]		1
[Row 1] CMDOSE		220

Variable	Old Value	New Value
[CMDOSE]		
[Row 1] CMQUANT [CMQUANT]		1
[Row 1] CMDOSFRM [CMDOSFRM]		TABLET
[Row 1] CMTOTDOS [CMTOTDOS]		220
[Row 1] CMROUTE [CMROUTE]		ORAL
[Row 1] CMDOSFRQ [CMDOSFRQ]		ONCE
[Row 1] CMSTDAT [CMSTDAT]		15-Jun-2018
[Row 1] CMSTTNK [CMSTTNK]		Yes
[Row 1] CMENDAT [CMENDAT]		15-Jun-2018
[Row 1] CMENTNK [CMENTNK]		Yes
[Row 2] CMNUM [CMNUM]		2
[Row 2] CMTRT [CMTRT]		IBUPROFEN
[Row 2] CMINDC [CMINDC]		Medical History
[Row 2] CMMHNUM [CMMHNUM]		1
[Row 2] CMDOSE [CMDOSE]		250
[Row 2] CMQUANT [CMQUANT]		2
[Row 2] CMDOSFRM [CMDOSFRM]		TABLET
[Row 2] CMTOTDOS [CMTOTDOS]		500
[Row 2] CMROUTE [CMROUTE]		ORAL
[Row 2] CMDOSFRQ [CMDOSFRQ]		ONCE
[Row 2] CMSTDAT [CMSTDAT]		12-Jun-2018
[Row 2] CMSTTNK [CMSTTNK]		Yes

Variable	Old Value	New Value
[Row 2] CMENDAT [CMENDAT]		12-Jun-2018
[Row 2] CMENTNK [CMENTNK]		Yes
[Row 3] CMNUM [CMNUM]		3
[Row 3] CMTRT [CMTRT]		ACETAMINOPHEN
[Row 3] CMINDC [CMINDC]		Adverse Event
[Row 3] CMAENUM [CMAENUM]		1
[Row 3] CMDOSE [CMDOSE]		325
[Row 3] CMDOSU [CMDOSU]		mg
[Row 3] CMQUANT [CMQUANT]		2
[Row 3] CMDOSFRM [CMDOSFRM]		TABLET
[Row 3] CMTOTDOS [CMTOTDOS]		650
[Row 3] CMTOTUN [CMTOTUN]		mg
[Row 3] CMROUTE [CMROUTE]		ORAL
[Row 3] CMDOSFRQ [CMDOSFRQ]		ONCE
[Row 3] CMSTDAT [CMSTDAT]		23-Jun-2018
[Row 3] CMSTTIM [CMSTTIM]		17:35
[Row 3] CMENDAT [CMENDAT]		23-Jun-2018
[Row 3] CMENTIM [CMENTIM]		17:35

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-Aug-2018 10:34 AM PDT (UTC-07:00)	Form marked as Complete
System	27-Jun-2018 02:16 PM PDT (UTC-07:00)	Form marked as Not Complete
System	27-Jun-2018 02:16 PM PDT (UTC-07:00)	Form marked as Complete
System	25-Jun-2018 08:21 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: All Visits
FORM: Concomitant Medications

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	25-Oct-2018 11:23 AM PDT (UTC-07:00)	Form marked as "Form Monitored".
(b) (6) algopharm.com (b) (6) (b) (6)	11-Oct-2018 02:30 PM PDT (UTC-07:00)	Updated information (Form unmarked as "Form Monitored"). - ESignature
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 02:36 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: All Visits
FORM: Concomitant Medications

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 2] CMTOTUN	Data Updated [06-Aug-2018 10:34 AM	27-Jun-2018 02:16 PM	06-Aug-2018 10:34 AM

ID	Variable	Responses/Reasons	Opened	Closed
		by (b) (6) vinceandassociates.com ((b) (6) (b) (6)		
	Description			
	New: Total Dose Unit is missing, please review **Old:** **By:** 27-Jun-2018 02:16 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] CMTOTUN	Data Updated [06-Aug-2018 10:34 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	27-Jun-2018 02:16 PM	06-Aug-2018 10:34 AM
	Description			
	New: Total Dose Unit is missing, please review **Old:** **By:** 27-Jun-2018 02:16 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 2] CMDOSOTH2	Data Updated [06-Aug-2018 10:33 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	27-Jun-2018 02:16 PM	06-Aug-2018 10:33 AM
	Description			
	New: Frequency is missing, please review **Old:** **By:** 27-Jun-2018 02:16 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] CMDOSOTH2	Data Updated [06-Aug-2018 10:33 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	27-Jun-2018 02:16 PM	06-Aug-2018 10:33 AM
	Description			
	New: Frequency is missing, please review **Old:** **By:** 27-Jun-2018 02:16 PM (b) (6) vinceandassociates.com ((b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 2] CMDOSU	Data Updated [06-Aug-2018 10:33 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	27-Jun-2018 02:16 PM	06-Aug-2018 10:33 AM
	Description			
	New: Dose Unit is missing, please review **Old:** **By:** 27-Jun-2018 02:16 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] CMDOSU	Data Updated [06-Aug-2018 10:33 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	27-Jun-2018 02:16 PM	06-Aug-2018 10:33 AM
	Description			
	New: Dose Unit is missing, please review **Old:** **By:** 27-Jun-2018 02:16 PM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

VISIT: All Visits
FORM: Concomitant Medications

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