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Site:	Site A
Group:	Group A
Medrio ID:	0047
Subject Identifier:	01-126
Status:	Completed
Timezone:	Pacific Standard Time
Study Name:	CEG-P9-153

SUBJECT INFORMATION HISTORY

Object	Date Time	User	Old Value	New Value
Subject Status	01-Aug-2018 07:34 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)	Enrolled	Completed
Subject ID	09-Jul-2018 11:39 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		01-126
Medrio ID	09-Jul-2018 11:39 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		47
Subject Status	09-Jul-2018 11:39 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Enrolled
Site	09-Jul-2018 11:39 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Site A
Group	09-Jul-2018 11:39 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Group A
ePRO Enabled	09-Jul-2018 11:39 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		No

SUBJECT LOCKING HISTORY

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

VISIT LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Screening
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Screening
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:39 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		21-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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Visit Date

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Visit Date

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

CLINICAL DATA

VISIT: Screening
FORM: ICF

Was the most current IRB approved version of the Informed Consent signed by the subject? [DSYN]	Yes

Row 1	
Date Subject Signed ICF: (Original signature) [DSDAT]	21-Jun-2018
ICF Version: [DSVERS]	v3 ICF CEG-P9-153
ICF Version Date: [DSVDAT]	01-May-2018

AUDIT TRAIL

VISIT: Screening
FORM: ICF

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:39 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]		21-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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ICF

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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: ICF

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

CLINICAL DATA

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

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

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

AUDIT TRAIL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:39 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

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

CLINICAL DATA

VISIT: Screening
FORM: Demographics

Visit Date: [DMDAT]	21-Jun-2018
Date of Birth: [DMBRTHDAT]	(b) (6)
Age: [DMAGE]	44
Age Unit: [DMAGEU]	YEARS
Gender: [DMSEX]	F
Ethnicity: [DMETHNIC]	NOT HISPANIC OR LATINO
Race: [DMRACE]	WHITE
Other, Specify: [DMRCOT]	

AUDIT TRAIL

VISIT: Screening
FORM: Demographics

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DMDAT [DMDAT]		21-Jun-2018
DMBRTHDAT [DMBRTHDAT]		[redacted]
DMAGE [DMAGE]		44
DMAGEU [DMAGEU]		YEARS
DMSEX [DMSEX]		F
DMETHNIC [DMETHNIC]		NOT HISPANIC OR LATINO
DMRACE [DMRACE]		WHITE

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Demographics

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:40 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Demographics

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Demographics

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

CLINICAL DATA

VISIT: Screening
FORM: Medical History

Does the subject have any relevant medical or surgical history (including drug allergies)? [MHYN]	Yes
Date of Visit: [MHDAT]	21-Jun-2018
Row 1	
Medical History #: [MHNUM]	1
Body System Code: [MHSCAT]	Psychiatric/Neurologic
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	HEADACHE - INTERMITTENT
Onset Date: [MHSTDAT]	UN-UNK-2017

Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	Yes
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 2	
Medical History #: [MHNUM]	2
Body System Code: [MHSCAT]	Genitourinary/Renal
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	ENDOMETRIOSIS
Onset Date: [MHSTDAT]	UN-UNK-1998
Date Resolved: [MHENDAT]	UN-UNK-2005
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]	TOTAL ABDOMINAL HYSTERECTOMY
Onset Date: [MHSTDAT]	UN-UNK-2005

Date Resolved: [MHENDAT]	UN-UNK-2005
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 4	
Medical History #: [MHNUM]	4
Body System Code: [MHSCAT]	Surgical
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	BILATERAL BREAST AUGMENTATION FOR COSMETIC REASONS
Onset Date: [MHSTDAT]	UN-UNK-2006
Date Resolved: [MHENDAT]	UN-UNK-2006
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant
Row 5	
Medical History #: [MHNUM]	5
Body System Code: [MHSCAT]	Psychiatric/Neurologic
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	CONCUSSION
Onset Date: [MHSTDAT]	UN-UNK-2014

Date Resolved: [MHENDAT]	UN-UNK-2014
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	Not Clinically Sigficant

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

AUDIT TRAIL

VISIT: Screening
FORM: Medical History

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:52 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
MHYN [MHYN]		Yes
MHDAT [MHDAT]		21-Jun-2018
[Row 1] MHNUM [MHNUM]		1
[Row 1] MHSCAT [MHSCAT]		Psychiatric/Neurologic
[Row 1] MHCAT [MHSCAT]		HEADACHE - INTERMITTENT
[Row 1] MHSTDAT [MHSTDAT]		UN-UNK-2017
[Row 1] MHONGO [MHONGO]		Yes
[Row 1] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 2] MHNUM [MHNUM]		2

Variable	Old Value	New Value
[Row 2] MHSCAT [MHSCAT]		Genitourinary/Renal
[Row 2] MHCAT [MHSCAT]		ENDOMETRIOSIS
[Row 2] MHSTDAT [MHSTDAT]		UN-UNK-1998
[Row 2] MHENDAT [MHENDAT]		UN-UNK-2005
[Row 2] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 3] MHNUM [MHNUM]		3
[Row 3] MHSCAT [MHSCAT]		Surgical
[Row 3] MHCAT [MHSCAT]		TOTAL ABDOMINAL HYSTERECTOMY
[Row 3] MHSTDAT [MHSTDAT]		UN-UNK-2005
[Row 3] MHENDAT [MHENDAT]		UN-UNK-2005
[Row 3] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 4] MHNUM [MHNUM]		4
[Row 4] MHSCAT [MHSCAT]		Surgical
[Row 4] MHCAT [MHSCAT]		BILATERAL BREAST AUGMENTATION FOR COSMETIC REASONS
[Row 4] MHSTDAT [MHSTDAT]		UN-UNK-2006
[Row 4] MHENDAT [MHENDAT]		UN-UNK-2006
[Row 4] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
[Row 5] MHNUM [MHNUM]		5
[Row 5] MHSCAT [MHSCAT]		Psychiatric/Neurologic
[Row 5] MHCAT [MHSCAT]		CONCUSSION
[Row 5] MHSTDAT [MHSTDAT]		UN-UNK-2014

Variable	Old Value	New Value
[Row 5] MHENDAT [MHENDAT]		UN-UNK-2014
[Row 5] MHCLSIG [MHCLSIG]		Not Clinically Sigficant
MHSMK [MHSMK]		Yes
MHRECUSE [MHRECUSE]		No

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Medical History

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:52 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Medical History

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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]	21-Jun-2018
Completion Time: [PETIM]	11:35
Row 1	
Body System Examined: [PETEST]	GENERAL APPEARANCE
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 2	
Body System Examined: [PETEST]	HEENT
Not done: [PESTAT]	

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

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

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

AUDIT TRAIL

VISIT: Screening
FORM: Complete Physical Examination

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	09-Jul-2018 11:53 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN [PEYN]		Yes

Variable	Old Value	New Value
PEDAT [PEDAT]		21-Jun-2018
PETIM [PETIM]		11:35
[Row 1] PETEST [PETEST]		GENERAL APPEARANCE
[Row 1] PEORRES [PEORRES]		NORMAL
[Row 2] PETEST [PETEST]		HEENT
[Row 2] PEORRES [PEORRES]		NORMAL
[Row 3] PETEST [PETEST]		NECK/THYROID
[Row 3] PEORRES [PEORRES]		NORMAL
[Row 4] PETEST [PETEST]		CARDIOVASCULAR
[Row 4] PEORRES [PEORRES]		NORMAL
[Row 5] PETEST [PETEST]		RESPIRATORY
[Row 5] PEORRES [PEORRES]		NORMAL
[Row 6] PETEST [PETEST]		GASTROINTESTINAL
[Row 6] PEORRES [PEORRES]		NORMAL
[Row 7] PETEST [PETEST]		NEUROLOGICAL
[Row 7] PEORRES [PEORRES]		NORMAL
[Row 8] PETEST [PETEST]		MUSCULOSKELETAL/EXTREMITIES
[Row 8] PEORRES [PEORRES]		NORMAL
[Row 9] PETEST [PETEST]		SKIN
[Row 9] PEORRES [PEORRES]		NORMAL
[Row 10] PETEST [PETEST]		OTHER

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Complete Physical Examination

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:53 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Complete Physical Examination

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Complete Physical Examination

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

CLINICAL DATA

VISIT: Screening
FORM: Height, Weight and BMI

Was the assessment performed? [VSYN]	Yes
Visit Date: [VSDAT]	21-Jun-2018
Height: [VSHGT]	164.0
Weight: [VSWGT]	56.1
BMI: [VSBMI]	20.9

AUDIT TRAIL

VISIT: Screening
FORM: Height, Weight and BMI

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:43 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSYN [VSYN]		Yes
VSDAT [VSDAT]		21-Jun-2018
VSHGT [VSHGT]		164.0
VSWGT [VSWGT]		56.1
VSBMI [VSBMI]		20.9

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	09-Jul-2018 11:43 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Height, Weight and BMI

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Height, Weight and BMI

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

CLINICAL DATA

VISIT: Screening
FORM: Serology Lab Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes

Date of collection: [LBDAT]	21-Jun-2018
Time of Collection: [LBTIM]	11:17
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: Serology Lab Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:47 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN [LBYN]		Yes
LBDAT [LBDAT]		21-Jun-2018
LBTIM [LBTIM]		11:17
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	09-Jul-2018 11:47 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Serology Lab Evaluation

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Serology Lab Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Serum Pregnancy Test

Was Serum Pregnancy Test performed? [LBHCGYN]	Yes

Date of collection: [LBDAT]	21-Jun-2018
Time of Collection: [LBTIM]	11:17
Time Unknown: [LBTMNK]	

AUDIT TRAIL

VISIT: Screening
FORM: Serum Pregnancy Test

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:47 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBHCGYN [LBHCGYN]		Yes
LBDAT1 [LBDAT]		21-Jun-2018
LBTIM1 [LBTIM]		11:17

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serum Pregnancy Test

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:47 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:40 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Serum Pregnancy Test

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Serum Pregnancy Test

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

CLINICAL DATA

VISIT: Screening
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	11:07
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	21-Jun-2018

Time Taken: [VSTIM]	11:12
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.8
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	102
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	70

Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	79
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	12
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Screening
FORM: Vital Signs

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:45 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]		11:07
VS1DAT [VSDAT]		21-Jun-2018
VSTIM [VSTIM]		11:12
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.8
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		102
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		70
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[VSCLSIG]		
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		79
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		12
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:45 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Vital Signs

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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-Jun-2018
Time of Collection: [LBTIM]	11:00
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:46 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		21-Jun-2018
LBTIM3 [LBTIM]		11:00
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	09-Jul-2018 11:46 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Cotinine Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-Jun-2018
Time of Collection: [LBTIM]	11:00
Time Unknown: [LBTMNK]	
Is the result within range? [LBNRIND]	No

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

AUDIT TRAIL

VISIT: Screening
FORM: Cotinine Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:46 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN4 [LBYN]		Yes
LBDAT4 [LBDAT]		21-Jun-2018
LBTIM4 [LBTIM]		11:00
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	09-Jul-2018 11:46 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Cotinine Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-Jun-2018
Time of Collection: [LBTIM]	11:17
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes
Row 1	
Test Name: [LBTEST]	

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

AUDIT TRAIL

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	09-Jul-2018 11:47 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		21-Jun-2018
LBTIM5 [LBTIM]		11:17
LBNRIND5 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:47 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Hematology Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-Jun-2018
Time of Collection: [LBTIM]	11:17
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	No
Row 1	
Test Name: [LBTEST]	HEMOGLOBIN

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

AUDIT TRAIL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:47 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		21-Jun-2018
LBTIM6 [LBTIM]		11:17
LBNRIND6 [LBNRIND]		No
[Row 1] LBTEST6 [LBTEST]		HEMOGLOBIN
[Row 1] LBCLSIG6 [LBCLSIG]		NCS

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Hematology Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:47 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Hematology Laboratory Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-Jun-2018
Time of Collection: [LBTIM]	11:00
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:46 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		21-Jun-2018
LBTIM7 [LBTIM]		11:00
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	09-Jul-2018 11:46 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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]	No
Date of collection: [LBDAT]	
Time of Collection: [LBTIM]	
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	

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

AUDIT TRAIL

VISIT: Screening
FORM: Endocrinology Evaluation

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:48 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN5 [LBYN]		No

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Endocrinology Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	11-Sep-2018 11:56 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:48 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:48 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:40 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Endocrinology Evaluation

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Endocrinology Evaluation

ID	Variable	Responses/Reasons	Opened	Closed
	LBYN5	NOT APPLICABLE TO THIS SUBJECT [09-Jul-2018 11:49 AM by (b) (6) vinceandassociates.com (b) (6) Response satisfies query [11-Sep-2018 11:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	09-Jul-2018 11:48 AM	11-Sep-2018 11:56 AM
	Description			
	New: Laboratory assessment was not performed as specified in the protocol; please clarify **Old:** **By:** 09-Jul-2018 11:48 AM (b) (6) algopharm.com (b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: Endocrinology Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: ECG Test Results

Was the ECG performed? [EGYN]	Yes
Date: [EGDAT]	21-Jun-2018
Visit: [EGVIS]	Screening
Row 1	
Time: [EGTIM]	11:06
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	57
PR Interval: [EGPR]	141
QRS Interval: [EGQRS]	93
QT Interval: [EGQT]	424
QTcB Interval: [EGQTCB]	413

QTcF: [EGQTCF]	417
Clinical Significance as per MD: [EGCLSIG]	NORMAL
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Screening
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:45 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT [EGDAT]		21-Jun-2018
EGVIS [EGVIS]		Screening
[Row 1] EG1TIM [EGTIM]		11:06
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		57
[Row 1] EG1PR [EGPR]		141
[Row 1] EG1QRS [EGQRS]		93
[Row 1] EG1QT [EGQT]		424
[Row 1] EGQTCB [EGQTCB]		413
[Row 1] EG1QTCF [EGQTCF]		417
[Row 1] EG1CLSIG [EGCLSIG]		NORMAL

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: ECG Test Results

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:45 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ECG Test Results

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: ECG Test Results

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

CLINICAL DATA

VISIT: Screening
FORM: Female Contraceptive Method

Visit Date [SCDAT]	21-Jun-2018

Childbearing Potential: [SCSTATUS]	NON-CHILDBEARING POTENTIAL
Is subject considered post-menopausal? [SCPOST]	No
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]	Hysterectomy
Procedure Date: [SCPRODAT]	UN-UNK-2005

AUDIT TRAIL

VISIT: Screening
FORM: Female Contraceptive Method

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:43 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SCDAT [SCDAT]		21-Jun-2018
SC1STATUS [SCSTATUS]		NON-CHILDBEARING POTENTIAL
SC1POST [SCPOST]		No
[Row 1] SCSUR [SCSUR]		Hysterectomy

Variable	Old Value	New Value
[Row 1] SCPRODAT [SCPRODAT]		UN-UNK-2005

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Female Contraceptive Method

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:43 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:40 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Female Contraceptive Method

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Female Contraceptive Method

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algopharm.com	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: Tobacco Use

Row 1	
Type of tobacco used? [SUTRT]	Cigarette(s)
Frequency: [SUFRQ]	Current
Start Date: [SUSTDAT]	UN-UNK-1992
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	
Daily Use: [SUDYUS]	15
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	09-Jul-2018 11:41 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

Variable	Old Value	New Value
[Row 1] SUSTDAT1 [SUSTDAT]		UN-UNK-1992
[Row 1] SUDYUS1 [SUDYUS]		15
[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
[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	17-Jul-2018 02:24 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:41 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:41 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Tobacco Use

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Tobacco Use

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] SUWKUS1	NOT APPLICABLE [09-Jul-2018 11:42 AM by (b) (6) vinceandassociates.com (b) (6) Response satisfies query [17-Jul-2018 02:24 PM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	09-Jul-2018 11:41 AM	17-Jul-2018 02:24 PM
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 09-Jul-2018 11:41 AM (b) (6) vinceandassociates.com (b) (6)			
	[Row 1] SUMONUS1	NOT APPLICABLE [09-Jul-2018 11:42 AM by (b) (6) vinceandass	09-Jul-2018 11:41 AM	17-Jul-2018 02:24 PM

ID	Variable	Responses/Reasons	Opened	Closed
		ociates.com ([redacted] Response satisfies query [17-Jul-2018 02:24 PM by [redacted] vinceandassociates.com ([redacted] [redacted]		
	Description			
	New: Monthly Use is missing, please review **Old:** **By:** 09-Jul-2018 11:41 AM [redacted] vinceandassociates.com ([redacted]			
	[Row 1] SUYRUS1	NOT APPLICABLE [09-Jul-2018 11:41 AM by [redacted] vinceandassociates.com ([redacted] Response satisfies query [17-Jul-2018 02:24 PM by [redacted] vinceandassociates.com ([redacted] [redacted]	09-Jul-2018 11:41 AM	17-Jul-2018 02:24 PM
	Description			
	New: Yearly Use is missing, please review **Old:** **By:** 09-Jul-2018 11:41 AM [redacted] vinceandassociates.com ([redacted]			

LOCKING HISTORY

VISIT: Screening
FORM: Tobacco Use

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			[redacted] algopharm.com ([redacted]	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]	06-Jul-2018

AUDIT TRAIL

VISIT: Day -1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:53 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		06-Jul-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	09-Jul-2018 11:53 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day -1
FORM: Urine Pregnancy Test

Was Urine Pregnancy Test performed? [LBHCGYN]	Yes
Date of collection: [LBDAT]	06-Jul-2018
Time of Collection: [LBTIM]	07:27
Time Unknown: [LBTMNK]	

AUDIT TRAIL

VISIT: Day -1
FORM: Urine Pregnancy Test

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:54 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBHCGYN1 [LBHCGYN]		Yes
LBDAT2 [LBDAT]		06-Jul-2018
LBTIM2 [LBTIM]		07:27

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Urine Pregnancy Test

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	09-Jul-2018 11:54 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:40 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Urine Pregnancy Test

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Urine Pregnancy Test

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	07:35
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	06-Jul-2018
Time Taken: [VSTIM]	07:42
Time Unknown: [VSTMNK]	

Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	37.2
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	132
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]	80
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	13
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Day -1
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	09-Jul-2018 11:54 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No

Variable	Old Value	New Value
VSTIMS [VS1TIMS]		07:35
VS1DAT [VSDAT]		06-Jul-2018
VSTIM [VSTIM]		07:42
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		37.2
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		132
[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]		80
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		13

Variable	Old Value	New Value
[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	09-Jul-2018 11:54 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Vital Signs

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Vital Signs

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

CLINICAL DATA

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

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	06-Jul-2018
Time of Collection: [LBTIM]	07:27
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:55 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		06-Jul-2018
LBTIM3 [LBTIM]		07:27
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	09-Jul-2018 11:55 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day -1
FORM: Symptom Directed Physical Exam

Was physical examination performed? [PEYN]	No

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

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

If Other, please specify: [PEOTHSP]	

AUDIT TRAIL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	09-Jul-2018 11:55 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

User	Date/Time	Change
System	09-Jul-2018 11:55 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

VISIT: Day 1
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	07-Jul-2018

AUDIT TRAIL

VISIT: Day 1
FORM: Visit Date

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:55 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		07-Jul-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	09-Jul-2018 11:55 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Visit Date

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	08-Aug-2018 12:19 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]	07-Jul-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:10
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:13
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:11

Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	10:16
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:03
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:09
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:21
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:27
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:59
Number of Butts Returned: [EXCIGRET]	1

Time Returned: [EXTIMRET]	13:04
Row 6	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:05
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:08

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	10-Jul-2018 11:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		07-Jul-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM [EXTIM]		09:10
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		09:13
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1

Variable	Old Value	New Value
[Row 2] EXTIM [EXTIM]		10:11
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		10:16
[Row 3] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		11:03
[Row 3] EXCIGRET [EXCIGRET]		1
[Row 3] EXTIMRET [EXTIMRET]		11:09
[Row 4] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		12:21
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		12:27
[Row 5] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD [EXDSPD]		1
[Row 5] EXTIM [EXTIM]		12:59
[Row 5] EXCIGRET [EXCIGRET]		1
[Row 5] EXTIMRET [EXTIMRET]		13:04
[Row 6] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD [EXDSPD]		1
[Row 6] EXTIM [EXTIM]		13:05

Variable	Old Value	New Value
[Row 6] EXCIGRET [EXCIGRET]		1
[Row 6] EXTIMRET [EXTIMRET]		13:08

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	10-Jul-2018 11:49 AM PDT (UTC-07:00)	Form marked as Complete
System	10-Jul-2018 11:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:03 PM 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) algo pharm.com (b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

AD LIB VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG	
Date of Visit: [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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected

User	Date/Time	Change
System	09-Jul-2018 11:39 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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]	07-Jul-2018
Randomization Number: [DSNUM]	1043
Sequence Group [DSRNGRP]	BCA

AUDIT TRAIL

VISIT: Day 1
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	10-Jul-2018 11:35 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
DSRNGRP [DSRNGRP]		BCA
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:56 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		07-Jul-2018
DSRNUM [DSNUM]		1043

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	10-Jul-2018 11:35 AM PDT (UTC-07:00)	Form marked as Complete
(b) (6) vinceandassociates.com ((b) (6)	09-Jul-2018 11:56 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:56 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Randomization

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Randomization

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

CLINICAL DATA

VISIT: Day 1
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 1
FORM: Use Product Again - VAS

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	09-Jul-2018 11:56 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	09-Jul-2018 11:56 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Use Product Again - VAS

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Use Product Again - VAS

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

CLINICAL DATA

VISIT: Day 2
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 2
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	09-Jul-2018 11:56 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		08-Jul-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	09-Jul-2018 11:56 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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) 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 - Nicorette Dosing Log

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

Date of Visit: [EXDAT]	08-Jul-2018

Row 1	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:10
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	09:13

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	10-Jul-2018 11:59 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT2 [EXDAT]		08-Jul-2018
[Row 1] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXDSPD2 [EXDSPD]		1
[Row 1] EXTIM2 [EXTIM]		09:10
[Row 1] EXNICRET [EXNICRET]		1
[Row 1] EXTIMRET2 [EXTIMRET]		09:13

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	10-Jul-2018 11:59 AM PDT (UTC-07:00)	Form marked as Complete
System	10-Jul-2018 11:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:04 PM 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)	
Date/Time	09-Jul-2018 11:56 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	09-Jul-2018 11:56 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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) 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: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	09-Jul-2018

AUDIT TRAIL

VISIT: Day 3
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	10-Jul-2018 11:40 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		09-Jul-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	10-Jul-2018 11:40 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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]	09-Jul-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:10
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	09:12
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	09:57
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]	11:08
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:12
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:41
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:44

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	10-Jul-2018 12:07 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT1 [EXDAT]		09-Jul-2018
[Row 1] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD1 [EXDSPD]		1
[Row 1] EXTIM1 [EXTIM]		09:10
[Row 1] EXCIGRET1 [EXCIGRET]		1
[Row 1] EXTIMRET1		09:12

Variable	Old Value	New Value
[EXTIMRET]		
[Row 2] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD1 [EXDSPD]		1
[Row 2] EXTIM1 [EXTIM]		09:57
[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]		11:08
[Row 3] EXCIGRET1 [EXCIGRET]		1
[Row 3] EXTIMRET1 [EXTIMRET]		11:12
[Row 4] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD1 [EXDSPD]		1
[Row 4] EXTIM1 [EXTIM]		12:41
[Row 4] EXCIGRET1 [EXCIGRET]		1
[Row 4] EXTIMRET1 [EXTIMRET]		12:44

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	10-Jul-2018 12:07 PM PDT (UTC-07:00)	Form marked as Complete
System	10-Jul-2018 11:35 AM PDT (UTC-07:00)	Form marked as Not Complete

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:04 PM 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	10-Jul-2018 11:40 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	10-Jul-2018 11:40 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
FORM: Use Product Again - VAS

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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]	10-Jul-2018

AUDIT TRAIL

VISIT: Day 4
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 11:47 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		10-Jul-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	11-Jul-2018 11:47 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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]	10-Jul-2018
Randomization Number: [DSNUM]	2042
Sequence Group [DSRNGRP]	CAB

AUDIT TRAIL

VISIT: Day 4
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 12:01 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
DSRNGRP [DSRNGRP]		CAB
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 11:48 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		10-Jul-2018
DSRNUM [DSNUM]		2042

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	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Complete
(b) (6) vinceandassociates.com ((b) (6)	11-Jul-2018 11:48 AM PDT (UTC-07:00)	Form marked as Not Complete
System	11-Jul-2018 11:48 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
FORM: Randomization

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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]	10-Jul-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	09:10

Session End Time: [EXENTMB]	09:20

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 12:01 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT [EXNICDAT]		10-Jul-2018
[Row 1] EXPRDB [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB [EXSRTTIMB]		09:10
[Row 1] EXENTMB [EXENTMB]		09:20
EXBEV [EXBEV]		No

FORM STATUS CHANGE LOG

VISIT: Day 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	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Complete
System	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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
(b) (6) gmail.com (b) (6) (b) (6)	02-Aug-2018 01:06 PM 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) algopharm.com (b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

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

Session End Time: [EXENTMB]	15:11

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	12-Jul-2018 12:02 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT2 [EXNICDAT]		10-Jul-2018
[Row 1] EXPRDB2 [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB2 [EXSRTTIMB]		15:10
[Row 1] EXENTMB2 [EXENTMB]		15:11
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	12-Jul-2018 12:02 PM PDT (UTC-07:00)	Form marked as Complete
System	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:06 PM 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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) algo pharm.com (b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 12:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF [QSPERF]		Yes
QSUSE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	11-Jul-2018 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	11-Jul-2018 12:03 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF1 [QSPERF]		Yes
QSUSE_1 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	11-Jul-2018 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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	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: 1st Use - Direct Effects of Product Questionnaire

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	11-Jul-2018 12:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF_1 [QSPERF]		Yes
QSUSE_2 [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

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

User	Date/Time	Change
System	11-Jul-2018 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 12:03 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 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	11-Jul-2018 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

Use: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:08
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection

Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	
Time: [PKTIM]	
Not Done: [PKSTAT]	Yes
Time Unknown [PKACTNK]	
Comments: [PKCODE]	D - No Sample Collected due to difficult collection
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:17
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	10-Jul-2018

Time: [PKTIM]	09:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure

Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	09:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	10:42
Not Done: [PKSTAT]	

Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	11:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	11:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	10-Jul-2018

Time: [PKTIM]	12:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 11:55 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]		10-Jul-2018
[Row 1] PKTIM [PKTIM]		09:08
[Row 1] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKSTAT [PKSTAT]		Yes
[Row 2] PKCODE [PKCODE]		D - No Sample Collected due to difficult collection
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		10-Jul-2018
[Row 3] PKTIM [PKTIM]		09:15

Variable	Old Value	New Value
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		10-Jul-2018
[Row 4] PKTIM [PKTIM]		09:17
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		10-Jul-2018
[Row 5] PKTIM [PKTIM]		09:20
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		10-Jul-2018
[Row 6] PKTIM [PKTIM]		09:22
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		10-Jul-2018
[Row 7] PKTIM [PKTIM]		09:25
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		10-Jul-2018
[Row 8] PKTIM [PKTIM]		09:30
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		10-Jul-2018
[Row 9] PKTIM [PKTIM]		09:41
[Row 9] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		10-Jul-2018

Variable	Old Value	New Value
[Row 10] PKTIM [PKTIM]		09:55
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		10-Jul-2018
[Row 11] PKTIM [PKTIM]		10:10
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		10-Jul-2018
[Row 12] PKTIM [PKTIM]		10:42
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		10-Jul-2018
[Row 13] PKTIM [PKTIM]		11:10
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		10-Jul-2018
[Row 14] PKTIM [PKTIM]		11:40
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		10-Jul-2018
[Row 15] PKTIM [PKTIM]		12:10

FORM STATUS CHANGE LOG

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

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

User	Date/Time	Change
System	11-Jul-2018 11:55 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose

Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:16
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:22

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute

Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	15:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	16:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	16:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	17:40

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	10-Jul-2018
Time: [PKTIM]	18:10
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	17-Aug-2018 08:57 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 12] PKCODE1 [PKCODE]		B - Late due to previous procedure

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 12:02 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		10-Jul-2018
[Row 1] PKTIM1 [PKTIM]		15:05
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		10-Jul-2018
[Row 2] PKTIM1 [PKTIM]		15:12
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		10-Jul-2018
[Row 3] PKTIM1 [PKTIM]		15:16
[Row 3] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		10-Jul-2018
[Row 4] PKTIM1 [PKTIM]		15:17
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		10-Jul-2018
[Row 5] PKTIM1 [PKTIM]		15:20
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		10-Jul-2018

Variable	Old Value	New Value
[Row 6] PKTIM1 [PKTIM]		15:22
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		10-Jul-2018
[Row 7] PKTIM1 [PKTIM]		15:25
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		10-Jul-2018
[Row 8] PKTIM1 [PKTIM]		15:30
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		10-Jul-2018
[Row 9] PKTIM1 [PKTIM]		15:40
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		10-Jul-2018
[Row 10] PKTIM1 [PKTIM]		15:55
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		10-Jul-2018
[Row 11] PKTIM1 [PKTIM]		16:11
[Row 11] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		10-Jul-2018
[Row 12] PKTIM1 [PKTIM]		16:41
[Row 13] PKTPT1 [PKTPT]		120 minute

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

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	11-Jul-2018 12:02 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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)	19-Sep-2018 02:37 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

User	Date/Time	Status
(b) (6) vinceandassociates.com (b) (6)	17-Aug-2018 08:57 AM PDT (UTC-07:00)	Updated information (Form partially unmarked as "Form Monitored").(PKCODE1 [12])
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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) algo pharm.com (b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: Day 4
FORM: Use Product Again - VAS 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	11-Jul-2018 12:03 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 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	11-Jul-2018 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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	11-Jul-2018 12:03 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 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	11-Jul-2018 12:03 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 5
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	11-Jul-2018

AUDIT TRAIL

VISIT: Day 5
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 09:42 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		11-Jul-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	12-Jul-2018 09:42 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 5
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 5
FORM: Visit Date

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

CLINICAL DATA

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

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

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

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Not Expected
System	16-May-2018 03:05 PM PDT (UTC-07:00)	Form marked as Not Complete

CLINICAL DATA

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

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

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

Session End Time: [EXENTMB]	

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Row 1	
Puff: [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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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]	11-Jul-2018
Session Start Time: [EXSTTIM]	09:10
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:10:13
Puff End: [EXPFEN]	09:10:15
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2

Puff Begin: [EXPFBG]	09:10:46
Puff End: [EXPFEN]	09:10:49
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	09:11:15
Puff End: [EXPFEN]	09:11:18
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	09:11:45
Puff End: [EXPFEN]	09:11:48
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	09:12:16

Puff End: [EXPFEN]	09:12:19
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:12:45
Puff End: [EXPFEN]	09:12:48
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:13:15
Puff End: [EXPFEN]	09:13:18
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:13:45
Puff End: [EXPFEN]	09:13:48

Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	Yes
If yes, provide reason: [EXCOM]	CIGARETTE ENDED
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	12-Jul-2018 01:18 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATVLN [EXDATVLN]		11-Jul-2018
EXSTTIM [EXSTTIM]		09:10
[Row 1] EXPFF [EXPFF]		Puff 1
[Row 1] EXPFBG [EXPFBG]		09:10:13
[Row 1] EXPFEN [EXPFEN]		09:10:15
[Row 1] EXMISPF [EXMISPF]		No
[Row 2] EXPFF [EXPFF]		Puff 2
[Row 2] EXPFBG [EXPFBG]		09:10:46
[Row 2] EXPFEN [EXPFEN]		09:10:49
[Row 2] EXMISPF [EXMISPF]		No
[Row 3] EXPFF [EXPFF]		Puff 3
[Row 3] EXPFBG [EXPFBG]		09:11:15
[Row 3] EXPFEN [EXPFEN]		09:11:18
[Row 3] EXMISPF [EXMISPF]		No
[Row 4] EXPFF [EXPFF]		Puff 4
[Row 4] EXPFBG [EXPFBG]		09:11:45
[Row 4] EXPFEN [EXPFEN]		09:11:48
[Row 4] EXMISPF [EXMISPF]		No
[Row 5] EXPFF [EXPFF]		Puff 5
[Row 5] EXPFBG [EXPFBG]		09:12:16

Variable	Old Value	New Value
[Row 5] EXPFEN [EXPFEN]		09:12:19
[Row 5] EXMISPF [EXMISPF]		No
[Row 6] EXPFF [EXPFF]		Puff 6
[Row 6] EXPFBG [EXPFBG]		09:12:45
[Row 6] EXPFEN [EXPFEN]		09:12:48
[Row 6] EXMISPF [EXMISPF]		No
[Row 7] EXPFF [EXPFF]		Puff 7
[Row 7] EXPFBG [EXPFBG]		09:13:15
[Row 7] EXPFEN [EXPFEN]		09:13:18
[Row 7] EXMISPF [EXMISPF]		No
[Row 8] EXPFF [EXPFF]		Puff 8
[Row 8] EXPFBG [EXPFBG]		09:13:45
[Row 8] EXPFEN [EXPFEN]		09:13:48
[Row 8] EXMISPF [EXMISPF]		No
[Row 9] EXMISPF [EXMISPF]		Yes
[Row 9] EXCOM [EXCOM]		CIGARETTE ENDED
[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	12-Jul-2018 01:19 PM PDT (UTC-07:00)	Form marked as Complete
System	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:07 PM 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]	11-Jul-2018
Session Start Time: [EXSRTTIM]	15:10
Session End Time: [EXENDTIM]	15:11
Row 1	
Inhalation Begin: [EXINHBG]	15:10:03
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:05
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:10:14
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:15
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:10:17

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:18
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:10:41
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:43
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:11:00
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:03
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	15:11:24
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:27
Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	6

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 01:22 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX9DATB [EXDATB]		11-Jul-2018
EX9SRTTIM [EXSRTTIM]		15:10
EX9ENDTIM [EXENDTIM]		15:11
[Row 1] EX9INHBG [EXINHBG]		15:10:03
[Row 1] EX9INEN [EXINEN]		15:10:05
[Row 2] EX9INHBG [EXINHBG]		15:10:14
[Row 2] EX9INEN [EXINEN]		15:10:15
[Row 3] EX9INHBG [EXINHBG]		15:10:17
[Row 3] EX9INEN [EXINEN]		15:10:18
[Row 4] EX9INHBG [EXINHBG]		15:10:41
[Row 4] EX9INEN [EXINEN]		15:10:43
[Row 5] EX9INHBG [EXINHBG]		15:11:00
[Row 5] EX9INEN [EXINEN]		15:11:03
[Row 6] EX9INHBG [EXINHBG]		15:11:24

Variable	Old Value	New Value
[Row 6] EX9INEN [EXINEN]		15:11:27
EX9BEVB [EXBEVB]		No
EX9INTOT [EXINTOT]		6

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	12-Jul-2018 01:22 PM PDT (UTC-07:00)	Form marked as Complete
System	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:07 PM 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 09:49 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	12-Jul-2018 09:49 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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	12-Jul-2018 09:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF1 [QSPERF]		Yes
QSUSE_1 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jul-2018 09:49 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	12-Jul-2018 09:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF_1 [QSPERF]		Yes
QSUSE_2 [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jul-2018 09:49 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	08-Aug-2018 12:19 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	12-Jul-2018 09:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF2 [QSPERF]		Yes
QSUSE2 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jul-2018 09:49 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:19 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]	11-Jul-2018
Time: [PKTIM]	09:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:16

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute

Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	09:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	10:10

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 09:45 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]		11-Jul-2018
[Row 1] PKTIM [PKTIM]		09:05
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		11-Jul-2018
[Row 2] PKTIM [PKTIM]		09:12
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		11-Jul-2018
[Row 3] PKTIM [PKTIM]		09:16
[Row 3] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		11-Jul-2018
[Row 4] PKTIM [PKTIM]		09:17
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		11-Jul-2018
[Row 5] PKTIM [PKTIM]		09:20
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		11-Jul-2018
[Row 6] PKTIM [PKTIM]		09:22
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		11-Jul-2018
[Row 7] PKTIM [PKTIM]		09:25

Variable	Old Value	New Value
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		11-Jul-2018
[Row 8] PKTIM [PKTIM]		09:30
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		11-Jul-2018
[Row 9] PKTIM [PKTIM]		09:40
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		11-Jul-2018
[Row 10] PKTIM [PKTIM]		09:55
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		11-Jul-2018
[Row 11] PKTIM [PKTIM]		10:10
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		11-Jul-2018
[Row 12] PKTIM [PKTIM]		10:41
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		11-Jul-2018
[Row 13] PKTIM [PKTIM]		11:10
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		11-Jul-2018

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jul-2018 09:45 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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)	08-Aug-2018 12:19 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:12

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	15:56

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	16:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	16:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	11-Jul-2018
Time: [PKTIM]	18:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 09:48 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]		11-Jul-2018
[Row 1] PKTIM1 [PKTIM]		15:05
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		11-Jul-2018
[Row 2] PKTIM1 [PKTIM]		15:12
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		11-Jul-2018
[Row 3] PKTIM1 [PKTIM]		15:15
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		11-Jul-2018
[Row 4] PKTIM1 [PKTIM]		15:17
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		11-Jul-2018

Variable	Old Value	New Value
[Row 5] PKTIM1 [PKTIM]		15:20
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		11-Jul-2018
[Row 6] PKTIM1 [PKTIM]		15:22
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		11-Jul-2018
[Row 7] PKTIM1 [PKTIM]		15:25
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		11-Jul-2018
[Row 8] PKTIM1 [PKTIM]		15:30
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		11-Jul-2018
[Row 9] PKTIM1 [PKTIM]		15:40
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		11-Jul-2018
[Row 10] PKTIM1 [PKTIM]		15:56
[Row 10] PKCODE1 [PKCODE]		A - Late due to difficult collection
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		11-Jul-2018
[Row 11] PKTIM1 [PKTIM]		16:10
[Row 12] PKTPT1 [PKTPT]		90 minute

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jul-2018 09:48 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 09:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jul-2018 09:49 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Was Questionnaire performed? [QSPERF]	Yes

Use: [QSUSE]	2nd Use

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jul-2018 09:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jul-2018 09:49 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:19 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]	12-Jul-2018

AUDIT TRAIL

VISIT: Day 6
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	13-Jul-2018 12:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		12-Jul-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	13-Jul-2018 12:03 PM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day 6
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	18:20
Time Seated Unknown: [VSTIMSUN]	

Date: [VSDAT]	12-Jul-2018
Time Taken: [VSTIM]	18:25
Time Unknown: [VSTMNK]	

Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	37
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	109
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	

Result: [VSORRES]	77
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	69
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	14
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Day 6
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	13-Jul-2018 12:19 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		18:20
VS1DAT [VSDAT]		12-Jul-2018
VSTIM [VSTIM]		18:25
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		37
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		109
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		77
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		69
[Row 4] VSORRESU [VSORRESU]		beats/min

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

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	13-Jul-2018 12:19 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Vital Signs

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	12-Jul-2018
Time of Collection: [LBTIM]	18:10
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	13-Jul-2018 12:17 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		12-Jul-2018
LBTIM5 [LBTIM]		18:10
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	13-Jul-2018 12:17 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	12-Jul-2018
Time of Collection: [LBTIM]	18:10
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	13-Jul-2018 12:17 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		12-Jul-2018
LBTIM6 [LBTIM]		18:10
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	13-Jul-2018 12:17 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Hematology Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	12-Jul-2018
Time of Collection: [LBTIM]	07:08
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	13-Jul-2018 12:17 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		12-Jul-2018
LBTIM7 [LBTIM]		07:08
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	13-Jul-2018 12:17 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Urinalysis Laboratory Evaluation

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

CLINICAL DATA

VISIT: Day 6
FORM: Symptom Directed Physical Exam

Was physical examination performed? [PEYN]	Yes
Examination Date: [PEDAT]	12-Jul-2018
Completion Time: [PTIM]	18:38
ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM	
Row 1	
Body System Examined: [PETEST]	General Appearance
Not done: [PESTAT]	Yes
Examination Results: [PEORRES]	
Abnormal Findings: [PECLSIG]	
Row 2	
Body System Examined: [PETEST]	Respiratory
Not done: [PESTAT]	Yes

Examination Results: [PEORRES]	
Abnormal Findings: [PECLSIG]	
Row 3	
Body System Examined: [PETEST]	Cardiovascular
Not done: [PESTAT]	Yes
Examination Results: [PEORRES]	
Abnormal Findings: [PECLSIG]	
Row 4	
Body System Examined: [PETEST]	Gastrointestinal
Not done: [PESTAT]	Yes
Examination Results: [PEORRES]	
Abnormal Findings: [PECLSIG]	
Row 5	
Body System Examined: [PETEST]	Other
Not done: [PESTAT]	No
Examination Results: [PEORRES]	Abnormal NCS
Abnormal Findings: [PECLSIG]	ECCHYMOSES - LEFT FOREARM, ERYTHEMA, SWELLING - RIGHT ANTECUBITAL AREA
If Other, please specify: [PEOTHSP]	SKIN

AUDIT TRAIL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	13-Jul-2018 12:20 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [PEYN]		Yes
PE2DAT [PEDAT]		12-Jul-2018
PTIM1 [PTIM]		18:38
[Row 1] PETEST2 [PETEST]		General Appearance
[Row 1] PESTAT1 [PESTAT]		Yes
[Row 2] PETEST2 [PETEST]		Respiratory
[Row 2] PESTAT1 [PESTAT]		Yes
[Row 3] PETEST2 [PETEST]		Cardiovascular
[Row 3] PESTAT1 [PESTAT]		Yes
[Row 4] PETEST2 [PETEST]		Gastrointestinal
[Row 4] PESTAT1 [PESTAT]		Yes
[Row 5] PETEST2 [PETEST]		Other
[Row 5] PESTAT1 [PESTAT]		No
[Row 5] PEORRES1 [PEORRES]		Abnormal NCS
[Row 5] PECLSIG1 [PECLSIG]		ECCHYMOSES - LEFT FOREARM, ERYTHEMA, SWELLING - RIGHT ANTECUBITAL AREA
PEOTHSP1 [PEOTHSP]		SKIN

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Symptom Directed Physical Exam

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	13-Jul-2018 12:20 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

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

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	
Row 1	
Product: [EXPRDB]	
Session Start Time: [EXSRTTIMB]	
Session End Time: [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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

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

CLINICAL DATA

VISIT: Day 6
FORM: Part B - 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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) algopharm.com (b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

CONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	12-Jul-2018
Session Start Time: [EXSTTIM]	09:10
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	09:10:01
Puff End: [EXPFEN]	09:10:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2

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

Puff End: [EXPFEN]	09:12:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	09:12:30
Puff End: [EXPFEN]	09:12:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	09:13:00
Puff End: [EXPFEN]	09:13:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	09:13:30
Puff End: [EXPFEN]	09:13:33

Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	09:14:00
Puff End: [EXPFEN]	09:14:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 10	
Puff: [EXPFF]	Puff 10
Puff Begin: [EXPFBG]	09:14:30
Puff End: [EXPFEN]	09:14:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Did the subject consume any beverages during controlled product use? [EXBEVB]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	13-Jul-2018 01:36 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX8DATVLN [EXDATVLN]		12-Jul-2018
EX8STTIM [EXSTTIM]		09:10
[Row 1] EX8PFF [EXPFF]		Puff 1
[Row 1] EX8PFBG [EXPFBG]		09:10:01
[Row 1] EX8PFEN [EXPFEN]		09:10:04
[Row 1] EX8MISPF [EXMISPF]		No
[Row 2] EX8PFF [EXPFF]		Puff 2
[Row 2] EX8PFBG [EXPFBG]		09:10:30
[Row 2] EX8PFEN [EXPFEN]		09:10:33
[Row 2] EX8MISPF [EXMISPF]		No
[Row 3] EX8PFF [EXPFF]		Puff 3
[Row 3] EX8PFBG [EXPFBG]		09:11:00
[Row 3] EX8PFEN [EXPFEN]		09:11:03
[Row 3] EX8MISPF [EXMISPF]		No
[Row 4] EX8PFF [EXPFF]		Puff 4
[Row 4] EX8PFBG [EXPFBG]		09:11:30
[Row 4] EX8PFEN [EXPFEN]		09:11:33
[Row 4] EX8MISPF [EXMISPF]		No
[Row 5] EX8PFF [EXPFF]		Puff 5
[Row 5] EX8PFBG [EXPFBG]		09:12:00

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

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

FORM STATUS CHANGE LOG

VISIT: Day 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	13-Jul-2018 01:36 PM PDT (UTC-07:00)	Form marked as Complete
System	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:08 PM 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]	12-Jul-2018
Session Start Time: [EXSRTTIM]	15:10
Session End Time: [EXENDTIM]	15:13
Row 1	
Inhalation Begin: [EXINHBG]	15:10:00
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:03
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	15:10:29

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:30
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	15:10:51
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:10:53
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	15:11:18
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:20
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	15:11:58
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:11:59
Time Unknown: [EXTIMUNK]	

Row 6	
Inhalation Begin: [EXINHBG]	15:12:45
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:12:46
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	15:13:13
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:15
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	15:13:34
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	15:13:35
Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	8

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	13-Jul-2018 01:38 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATB [EXDATB]		12-Jul-2018
EXSRTTIM [EXSRTTIM]		15:10
EXENDTIM [EXENDTIM]		15:13
[Row 1] EXINHBG [EXINHBG]		15:10:00
[Row 1] EXINEN [EXINEN]		15:10:03
[Row 2] EXINHBG [EXINHBG]		15:10:29
[Row 2] EXINEN [EXINEN]		15:10:30
[Row 3] EXINHBG [EXINHBG]		15:10:51
[Row 3] EXINEN [EXINEN]		15:10:53
[Row 4] EXINHBG [EXINHBG]		15:11:18
[Row 4] EXINEN [EXINEN]		15:11:20
[Row 5] EXINHBG [EXINHBG]		15:11:58
[Row 5] EXINEN [EXINEN]		15:11:59
[Row 6] EXINHBG [EXINHBG]		15:12:45
[Row 6] EXINEN [EXINEN]		15:12:46
[Row 7] EXINHBG [EXINHBG]		15:13:13
[Row 7] EXINEN		15:13:15

Variable	Old Value	New Value
[EXINEN]		
[Row 8] EXINHBG [EXINHBG]		15:13:34
[Row 8] EXINEN [EXINEN]		15:13:35
EXBEVB [EXBEVB]		No
EXINTOT [EXINTOT]		8

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	13-Jul-2018 01:38 PM PDT (UTC-07:00)	Form marked as Complete
System	12-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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 01:08 PM 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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]	12-Jul-2018
Visit: [EGVIS]	Day 6

Row 1	
Time: [EGTIM]	18:18
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	56
PR Interval: [EGPR]	153
QRS Interval: [EGQRS]	83
QT Interval: [EGQT]	411
QTcB Interval: [EGQTCB]	397
QTcF: [EGQTCF]	402
Clinical Significance as per MD: [EGCLSIG]	NORMAL
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Day 6
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	13-Jul-2018 12:18 PM 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]		12-Jul-2018
EGVIS [EGVIS]		Day 6
[Row 1] EG1TIM [EGTIM]		18:18
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		56
[Row 1] EG1PR [EGPR]		153
[Row 1] EG1QRS [EGQRS]		83
[Row 1] EG1QT [EGQT]		411
[Row 1] EGQTCB [EGQTCB]		397
[Row 1] EG1QTCF [EGQTCF]		402
[Row 1] EG1CLSIG [EGCLSIG]		NORMAL

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: ECG Test Results

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	13-Jul-2018 12:18 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: ECG Test Results

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

CLINICAL DATA

VISIT: Day 6
FORM: 1st Use - 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	13-Jul-2018 12:22 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF [QSPERF]		Yes
QSUSE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	13-Jul-2018 12:22 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	13-Jul-2018 12:22 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

User	Date/Time	Change
System	13-Jul-2018 12:22 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Was Questionnaire performed at all time points: [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	13-Jul-2018 12:22 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF_1 [QSPERF]		Yes
QSUSE_2 [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	13-Jul-2018 12:22 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: 2nd Use - 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	13-Jul-2018 12:22 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	13-Jul-2018 12:22 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

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

CLINICAL DATA

VISIT: Day 6
FORM: End of Study

Visit Date [DSVDAT]	12-Jul-2018
Date of Completion or Discontinuation: [DSDAT]	12-Jul-2018
Date of Last Dose of Study Medication: [DSDOSDAT]	12-Jul-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	13-Jul-2018 12:22 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSVDAT1 [DSVDAT]		12-Jul-2018
DSDAT [DSDAT]		12-Jul-2018

Variable	Old Value	New Value
DSDOSDT [DSDOSDAT]		12-Jul-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	13-Jul-2018 12:22 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: End of Study

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: End of Study

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	12-Jul-2018
Time: [PKTIM]	09:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute

Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:22
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:25
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:30

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	09:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute

Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	10:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	10:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	11:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	13-Jul-2018 12:13 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]		12-Jul-2018
[Row 1] PKTIM [PKTIM]		09:05
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		12-Jul-2018
[Row 2] PKTIM [PKTIM]		09:12
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		12-Jul-2018
[Row 3] PKTIM [PKTIM]		09:15
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		12-Jul-2018
[Row 4] PKTIM [PKTIM]		09:17
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		12-Jul-2018
[Row 5] PKTIM [PKTIM]		09:20
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		12-Jul-2018
[Row 6] PKTIM [PKTIM]		09:22
[Row 7] PKTPT [PKTPT]		15 minute

Variable	Old Value	New Value
[Row 7] PKDAT [PKDAT]		12-Jul-2018
[Row 7] PKTIM [PKTIM]		09:25
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		12-Jul-2018
[Row 8] PKTIM [PKTIM]		09:30
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		12-Jul-2018
[Row 9] PKTIM [PKTIM]		09:40
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		12-Jul-2018
[Row 10] PKTIM [PKTIM]		09:55
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		12-Jul-2018
[Row 11] PKTIM [PKTIM]		10:10
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		12-Jul-2018
[Row 12] PKTIM [PKTIM]		10:40
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		12-Jul-2018
[Row 13] PKTIM [PKTIM]		11:10
[Row 14] PKTPT [PKTPT]		150 minute

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	13-Jul-2018 12:13 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

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

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

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	15:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	15:17
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

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

Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	15:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	15:41
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	15:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	16:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	16:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	17:40
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	12-Jul-2018
Time: [PKTIM]	18:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	13-Jul-2018 12:17 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		12-Jul-2018
[Row 1] PKTIM1 [PKTIM]		15:05
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		12-Jul-2018
[Row 2] PKTIM1 [PKTIM]		15:12
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		12-Jul-2018
[Row 3] PKTIM1 [PKTIM]		15:15
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		12-Jul-2018
[Row 4] PKTIM1 [PKTIM]		15:17
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		12-Jul-2018

Variable	Old Value	New Value
[Row 5] PKTIM1 [PKTIM]		15:20
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		12-Jul-2018
[Row 6] PKTIM1 [PKTIM]		15:22
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		12-Jul-2018
[Row 7] PKTIM1 [PKTIM]		15:25
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		12-Jul-2018
[Row 8] PKTIM1 [PKTIM]		15:30
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		12-Jul-2018
[Row 9] PKTIM1 [PKTIM]		15:41
[Row 9] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		12-Jul-2018
[Row 10] PKTIM1 [PKTIM]		15:55
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		12-Jul-2018
[Row 11] PKTIM1 [PKTIM]		16:10
[Row 12] PKTPT1 [PKTPT]		90 minute

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

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	13-Jul-2018 12:17 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	13-Jul-2018 12:23 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	13-Jul-2018 12:23 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Was Questionnaire performed? [QSPERF]	Yes

Use: [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	13-Jul-2018 12:23 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	13-Jul-2018 12:23 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Early Term
FORM: Visit Date

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Visit Date

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

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

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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)	13-Jul-2018 12:01 PM PDT (UTC-07:00)	Form marked as Not Expected
System	09-Jul-2018 11:39 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]	ECCHYMOSIS - LEFT FOREARM
Is this an SAE? [AESER]	No

Severity: [AESEV]	MILD
Frequency: [AEFREQ]	Continuous
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	No
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	10-Jul-2018
Onset Time: [AESTTIM]	13:40
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	15-Jul-2018
End Time: [AEENTIM]	
Time Unknown: [AEENTMNK]	Yes
Row 2	
AE Identifier: [AESPID]	2

Adverse Event Term: [AETERM]	PAIN AT IV INSERTION SITE - RIGHT ANTECUBITAL
Is this an SAE? [AESER]	No
Severity: [AESEV]	MILD
Frequency: [AEFREQ]	Continuous
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	No
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	11-Jul-2018
Onset Time: [AESTTIM]	17:10
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	12-Jul-2018
End Time: [AEENTIM]	15:00
Time Unknown: [AEENTMNK]	

AUDIT TRAIL

VISIT: All Visits
FORM: Adverse Events

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Aug-2018 01:24 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 1] AEENTMNK [AEENTMNK]	No	Yes
Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6)	
Date/Time	06-Aug-2018 11:32 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 1] AEOUT [AEOUT]		Resolved
[Row 1] AEENDAT [AEENDAT]		15-Jul-2018
[Row 2] AEOUT [AEOUT]		Resolved
[Row 2] AEENDAT [AEENDAT]		12-Jul-2018
[Row 2] AEENTIM [AEENTIM]		15:00
[Row 2] AEENTMNK [AEENTMNK]	No	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	13-Jul-2018 12:26 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
AEYN [AEYN]		Yes
[Row 1] AESPID [AESPID]		1

Variable	Old Value	New Value
[Row 1] AETERM [AETERM]		ECCHYMOSIS - LEFT FOREARM
[Row 1] AESER [AESER]		No
[Row 1] AESEV [AESEV]		MILD
[Row 1] AEFREQ [AEFREQ]		Continuous
[Row 1] AEACN [AEACN]		No Action Taken
[Row 1] AECONTRT [AECONTRT]		No
[Row 1] AEDIS [AEDIS]		No
[Row 1] AEREL [AEREL]		Unrelated
[Row 1] AETEAE [AETEAE]		No
[Row 1] AESTDAT [AESTDAT]		10-Jul-2018
[Row 1] AESTTIM [AESTTIM]		13:40
[Row 1] AEONGO [AEONGO]		No
[Row 1] AEENTMNK [AEENTMNK]		No
[Row 2] AESPID [AESPID]		2
[Row 2] AETERM [AETERM]		PAIN AT IV INSERTION SITE - RIGHT ANTECUBITAL
[Row 2] AESER [AESER]		No
[Row 2] AESEV [AESEV]		MILD
[Row 2] AEFREQ [AEFREQ]		Continuous
[Row 2] AEACN [AEACN]		No Action Taken
[Row 2] AECONTRT [AECONTRT]		No
[Row 2] AEDIS [AEDIS]		No

Variable	Old Value	New Value
[Row 2] AEREL [AEREL]		Unrelated
[Row 2] AETEAE [AETEAE]		No
[Row 2] AESTDAT [AESTDAT]		11-Jul-2018
[Row 2] AESTTIM [AESTTIM]		17:10
[Row 2] AEONGO [AEONGO]		No
[Row 2] AEENTMNK [AEENTMNK]		No

FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Adverse Events

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Aug-2018 01:24 PM PDT (UTC-07:00)	Form marked as Complete
System	13-Jul-2018 12:26 PM PDT (UTC-07:00)	Form marked as Not Complete
System	13-Jul-2018 12:26 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 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)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: All Visits
FORM: Adverse Events

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 2] AEENTIM	Data Updated [06-Aug-2018 11:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	13-Jul-2018 12:26 PM	06-Aug-2018 11:32 AM
	Description			
	New: Time is missing, please review **Old:** **By:** 13-Jul-2018 12:26 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] AEENTIM	time unk [06-Aug-2018 11:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) Data Updated [07-Aug-2018 01:24 PM by (b) (6) vinceandassociates.com ((b) (6)	13-Jul-2018 12:26 PM	07-Aug-2018 01:24 PM
	Description			
	New: Time is missing, please review **Old:** **By:** 13-Jul-2018 12:26 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 2] AEOUT	Data Updated [06-Aug-2018 11:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	13-Jul-2018 12:26 PM	06-Aug-2018 11:32 AM
	Description			
	New: Outcome is missing, please review **Old:** **By:** 13-Jul-2018 12:26 PM (b) (6) vinceandassociates.com ((b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] AEOUT	Data Updated [06-Aug-2018 11:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	13-Jul-2018 12:26 PM	06-Aug-2018 11:32 AM
	Description			
	New: Outcome is missing, please review **Old:** **By:** 13-Jul-2018 12:26 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 2] AEENDAT	Data Updated [06-Aug-2018 11:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	13-Jul-2018 12:26 PM	06-Aug-2018 11:32 AM
	Description			
	New: Date is missing, please review **Old:** **By:** 13-Jul-2018 12:26 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 1] AEENDAT	Data Updated [06-Aug-2018 11:32 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	13-Jul-2018 12:26 PM	06-Aug-2018 11:32 AM
	Description			
	New: Date is missing, please review **Old:** **By:** 13-Jul-2018 12:26 PM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

VISIT: All Visits
FORM: Adverse Events

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algopharm.com	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: 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]	NAPROXEN
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]	2
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	

Total Dose: [CMTOTDOS]	440
Unit: [CMTOTUN]	mg
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	PRN
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	UN-UNK-2017
Start Time: [CMSTTIM]	
Time Unknown [CMSTTNK]	Yes
End Date: [CMENDAT]	02-Jun-2018
End Time: [CMENTIM]	
Time Unknown [CMENTNK]	Yes
Ongoing? [CMONGO]	

AUDIT TRAIL

VISIT: All Visits
FORM: Concomitant Medications

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	10-Jul-2018 12:30 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]		NAPROXEN
[Row 1] CMINDC [CMINDC]		Medical History
[Row 1] CMMHNUM [CMMHNUM]		1
[Row 1] CMDOSE [CMDOSE]		220
[Row 1] CMDOSU [CMDOSU]		mg
[Row 1] CMQUANT [CMQUANT]		2
[Row 1] CMDOSFRM [CMDOSFRM]		TABLET
[Row 1] CMTOTDOS [CMTOTDOS]		440
[Row 1] CMTOTUN [CMTOTUN]		mg
[Row 1] CMROUTE [CMROUTE]		ORAL
[Row 1] CMDOSFRQ [CMDOSFRQ]		PRN
[Row 1] CMSTDAT [CMSTDAT]		UN-UNK-2017
[Row 1] CMSTTNK [CMSTTNK]		Yes
[Row 1] CMENDAT [CMENDAT]		02-Jun-2018
[Row 1] CMENTNK [CMENTNK]		Yes

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	10-Jul-2018 12:30 PM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 11:39 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: All Visits
FORM: Concomitant Medications

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	25-Oct-2018 11:23 AM PDT (UTC-07:00)	Form marked as "Form Monitored".
(b) (6) algopharm.com (b) (6) (b) (6)	11-Oct-2018 02:30 PM PDT (UTC-07:00)	Updated information (Form unmarked as "Form Monitored"). - ESignature
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	08-Aug-2018 12:33 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: All Visits
FORM: Concomitant Medications

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