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Site:	Site A
Group:	Group A
Medrio ID:	0026
Subject Identifier:	01-085
Status:	Completed
Timezone:	Pacific Standard Time
Study Name:	CEG-P9-153

SUBJECT INFORMATION HISTORY

Object	Date Time	User	Old Value	New Value
Subject Status	13-Jun-2018 09:22 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)	Enrolled	Completed
Subject ID	31-May-2018 09:34 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		01-085
Medrio ID	31-May-2018 09:34 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		26
Subject Status	31-May-2018 09:34 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Enrolled
Site	31-May-2018 09:34 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Site A
Group	31-May-2018 09:34 AM PDT (UTC-07:00)	(b) (6) vinceandassociates.com ((b) (6)		Group A
ePRO Enabled	31-May-2018 09:34 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 5	Locked	26-Oct-2018 01:27 PM PDT (UTC-07:00)	(b) (6) algopharm.com ((b) (6) (b) (6)
Day 4	Locked	26-Oct-2018 01:27 PM PDT (UTC-07:00)	(b) (6) algopharm.com ((b) (6) (b) (6)
Day 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 2	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 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-May-2018

AUDIT TRAIL

VISIT: Screening
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:12 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		21-May-2018

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Visit Date

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:12 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Visit Date

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Visit Date

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

CLINICAL DATA

VISIT: Screening
FORM: ICF

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

AUDIT TRAIL

VISIT: Screening
FORM: ICF

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	31-May-2018 10:24 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DSYN [DSYN]		Yes
[Row 1] DSDATE [DSDAT]		21-May-2018
[Row 1] DSVERS [DSVERS]		v3 ICF CEG-P9-153
[Row 1] DSVDAT [DSVDAT]		01-May-2018

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: ICF

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:24 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ICF

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: ICF

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

CLINICAL DATA

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

Does the subject meet all eligibility criteria required by the protocol? [IEYN]	Yes
If NO, please specify the inclusion and/or exclusion criteria number:	
Row 1	
Specify: [IECAT]	
Number: [IETESTCD]	
Comment: [IECOM]	

AUDIT TRAIL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:24 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
IEYN [IEYN]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:24 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: INCL/EXCL Criteria Summary

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

CLINICAL DATA

VISIT: Screening
FORM: Demographics

Visit Date: [DMDAT]	21-May-2018

Date of Birth: [DMBRTHDAT]	(b) (6)
Age: [DMAGE]	39
Age Unit: [DMAGEU]	YEARS
Gender: [DMSEX]	M
Ethnicity: [DMETHNIC]	NOT HISPANIC OR LATINO
Race: [DMRACE]	BLACK OR AFRICAN AMERICAN
Other, Specify: [DMRCOT]	

AUDIT TRAIL

VISIT: Screening
FORM: Demographics

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:26 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DMDAT [DMDAT]		21-May-2018
DMBRTHDAT [DMBRTHDAT]		(b) (6)
DMAGE [DMAGE]		39
DMAGEU [DMAGEU]		YEARS
DMSEX [DMSEX]		M
DMETHNIC [DMETHNIC]		NOT HISPANIC OR LATINO
DMRACE [DMRACE]		BLACK OR AFRICAN AMERICAN

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Demographics

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:26 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Demographics

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Demographics

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) algopharm.com ((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]	No
Date of Visit: [MHDAT]	

Row 1	
Medical History #: [MHNUM]	
Body System Code: [MHSCAT]	
If other, please specify: [MHOTHSP]	
Condition: [MHSCAT]	
Onset Date: [MHSTDAT]	
Date Resolved: [MHENDAT]	
Ongoing? [MHONGO]	
Safety Review: [MHCLSIG]	

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	31-May-2018 10:36 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
MHSMK [MHSMK]		Yes
MHRECUSE [MHRECUSE]		No
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:35 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
MHYN [MHYN]		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	31-May-2018 10:36 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 10:35 AM PDT (UTC-07:00)	Form marked as Not Complete
System	31-May-2018 10:35 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Medical History

ID	Variable	Responses/Reasons	Opened	Closed
	MHRECUSE	Data Updated [31-May-2018 10:36 AM by (b) (6) vinceandassociates.com ((b) (6)	31-May-2018 10:35 AM	31-May-2018 10:36 AM
	Description			
	New: Data is missing, please review **Old:** **By:** 31-May-2018 10:35 AM (b) (6) vinceandassociates.com ((b) (6)			
	MHSMK	Data Updated [31-May-2018 10:36 AM by (b) (6) vinceandassociates.com ((b) (6)	31-May-2018 10:35 AM	31-May-2018 10:36 AM
	Description			
	New: Data is missing, please review **Old:** **By:** 31-May-2018 10:35 AM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: Medical History

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

CLINICAL DATA

VISIT: Screening
FORM: Complete Physical Examination

Was the physical examination performed? [PEYN]	Yes
Examination Date: [PEDAT]	21-May-2018
Completion Time: [PETIM]	14:33
Row 1	
Body System Examined: [PETEST]	GENERAL APPEARANCE
Not done: [PESTAT]	
If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	NORMAL
Abnormal Findings: [PEDESC]	
Row 2	
Body System Examined: [PETEST]	HEENT
Not done: [PESTAT]	

If Other, please specify: [PEOTHSP]	
Examination Result: [PEORRES]	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 ([redacted]	
Date/Time	31-May-2018 10:36 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
PEYN [PEYN]		Yes
PEDAT [PEDAT]		21-May-2018

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Complete Physical Examination

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:36 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Complete Physical Examination

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Complete Physical Examination

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

CLINICAL DATA

VISIT: Screening
FORM: Height, Weight and BMI

Was the assessment performed? [VSYN]	Yes

Visit Date: [VSDAT]	21-May-2018
Height: [VSHGT]	187.0
Weight: [VSWGT]	75.1
BMI: [VSBMI]	21.5

AUDIT TRAIL

VISIT: Screening
FORM: Height, Weight and BMI

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:28 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
VSYN [VSYN]		Yes
VSDAT [VSDAT]		21-May-2018
VSHGT [VSHGT]		187.0
VSWGT [VSWGT]		75.1
VSBMI [VSBMI]		21.5

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Height, Weight and BMI

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:28 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Height, Weight and BMI

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: Height, Weight and BMI

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

CLINICAL DATA

VISIT: Screening
FORM: Serology Lab Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:39
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	31-May-2018 10:35 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN [LBYN]		Yes
LBDAT [LBDAT]		21-May-2018
LBTIM [LBTIM]		14:39
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	31-May-2018 10:35 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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)	07-Aug-2018 12:51 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]	
Date of collection: [LBDAT]	
Time of Collection: [LBTIM]	
Time Unknown: [LBTMNK]	

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Serum Pregnancy Test

User	Date/Time	Change
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Screening
FORM: Serum Pregnancy Test

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

CLINICAL DATA

VISIT: Screening
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	14:12
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	21-May-2018
Time Taken: [VSTIM]	14:17
Time Unknown: [VSTMNK]	

Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.2
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	121
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	78
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	56
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	16
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Screening
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:33 AM PDT (UTC-07:00)	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
VS1DAT [VSDAT]		21-May-2018

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:33 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		14:12
VSTIM [VSTIM]		14:17
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.2
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		121
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		78
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		56
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

Variable	Old Value	New Value
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		16
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:33 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 10:33 AM PDT (UTC-07:00)	Form marked as Not Complete
System	31-May-2018 10:33 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Vital Signs

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Vital Signs

ID	Variable	Responses/Reasons	Opened	Closed
	VS1DAT	Data Updated [31-May-2018 10:33 AM by (b) (6) vinceandassociates.com ((b) (6)	31-May-2018 10:33 AM	31-May-2018 10:33 AM
	Description			
	New: Date is missing, please review **Old:** **By:** 31-May-2018 10:33 AM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:03
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:34 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		21-May-2018
LBTIM3 [LBTIM]		14:03
LBNRIND3 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:34 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: UDS and Alcohol Laboratory Evaluation

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 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-May-2018
Time of Collection: [LBTIM]	14:03
Time Unknown: [LBTMNK]	
Is the result within range? [LBNRIND]	No
Row 1	
Test Name: [LBTEST]	Cotinine
Clinical Significance as per MD: [LBCLSIG]	NCS

AUDIT TRAIL

VISIT: Screening
FORM: Cotinine Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:34 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN4 [LBYN]		Yes
LBDAT4 [LBDAT]		21-May-2018
LBTIM4 [LBTIM]		14:03
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	31-May-2018 10:34 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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)	07-Aug-2018 12:51 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-May-2018
Time of Collection: [LBTIM]	14:39
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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	31-May-2018 10:34 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		21-May-2018
LBTIM5 [LBTIM]		14:39
LBNRIND5 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Chemistry Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:34 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Chemistry 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 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-May-2018
Time of Collection: [LBTIM]	14:39
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes
Row 1	
Test Name: [LBTEST]	

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

AUDIT TRAIL

VISIT: Screening
FORM: Hematology Laboratory Evaluation

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	31-May-2018 10:34 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		21-May-2018
LBTIM6 [LBTIM]		14:39
LBNRIND6 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Hematology Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:34 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Hematology 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	21-May-2018
Time of Collection: [LBTIM]	14:03
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes
Row 1	
Test Name: [LBTEST]	

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

AUDIT TRAIL

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:35 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		21-May-2018
LBTIM7 [LBTIM]		14:03
LBNRIND7 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Urinalysis Laboratory Evaluation

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:35 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 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) algo pharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: Screening
FORM: Endocrinology Evaluation

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

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Endocrinology Evaluation

User	Date/Time	Change
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Screening
FORM: Endocrinology Evaluation

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

CLINICAL DATA

VISIT: Screening
FORM: ECG Test Results

Was the ECG performed? [EGYN]	Yes
Date: [EGDAT]	21-May-2018
Visit: [EGVIS]	Screening
Row 1	
Time: [EGTIM]	14:10
Time Unknown: [EGTMNK]	

Position: [EGPOS]	SUPINE
VR: [EGVR]	51
PR Interval: [EGPR]	192
QRS Interval: [EGQRS]	98
QT Interval: [EGQT]	397
QTcB Interval: [EGQTCB]	366
QTcF: [EGQTCF]	376
Clinical Significance as per MD: [EGCLSIG]	NORMAL
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Screening
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:31 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT [EGDAT]		21-May-2018
EGVIS [EGVIS]		Screening
[Row 1] EG1TIM [EGTIM]		14:10
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR		51

Variable	Old Value	New Value
[EGVR]		
[Row 1] EG1PR [EGPR]		192
[Row 1] EG1QRS [EGQRS]		98
[Row 1] EG1QT [EGQT]		397
[Row 1] EGQTCB [EGQTCB]		366
[Row 1] EG1QTCF [EGQTCF]		376
[Row 1] EG1CLSIG [EGCLSIG]		NORMAL

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: ECG Test Results

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:31 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: ECG Test Results

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Screening
FORM: ECG Test Results

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

CLINICAL DATA

VISIT: Screening
FORM: Female Contraceptive Method

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

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

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Female Contraceptive Method

User	Date/Time	Change
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Screening
FORM: Female Contraceptive Method

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

CLINICAL DATA

VISIT: Screening
FORM: Tobacco Use

Row 1	
Type of tobacco used? [SUTRT]	Cigarette(s)
Frequency: [SUFRQ]	Current
Start Date: [SUSTDAT]	UN-UNK-1993
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	

Daily Use: [SUDYUS]	30
Row 2	
Type of tobacco used? [SUTRT]	Cigar(s)
Frequency: [SUFRQ]	Never
Start Date: [SUSTDAT]	
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	
Daily Use: [SUDYUS]	
Row 3	
Type of tobacco used? [SUTRT]	Cigarillo(s)
Frequency: [SUFRQ]	Never
Start Date: [SUSTDAT]	
End Date: [SUENDAT]	
Yearly Use: [SUYRUS]	
Monthly Use: [SUMONUS]	
Weekly Use: [SUWKUS]	

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

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

Daily Use: [SUDYUS]	

AUDIT TRAIL

VISIT: Screening
FORM: Tobacco Use

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	11-Jul-2018 10:55 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
[Row 1] SUTRT1 [SUTRT]		Cigarette(s)
[Row 1] SUFRQ1 [SUFRQ]		Current
[Row 1] SUSTDAT1 [SUSTDAT]		UN-UNK-1993
[Row 1] SUDYUS1 [SUDYUS]		30
[Row 2] SUTRT1 [SUTRT]		Cigar(s)
[Row 2] SUFRQ1 [SUFRQ]		Never
[Row 3] SUTRT1 [SUTRT]		Cigarillo(s)
[Row 3] SUFRQ1 [SUFRQ]		Never
[Row 4] SUTRT1 [SUTRT]		Chewing Tobacco
[Row 4] SUFRQ1 [SUFRQ]		Never
[Row 5] SUTRT1 [SUTRT]		Pipe(s)
[Row 5] SUFRQ1 [SUFRQ]		Never
[Row 6] SUTRT1 [SUTRT]		Nicotine Product(s): (patch, gum, etc)
[Row 6] SUFRQ1 [SUFRQ]		Never
[Row 7] SUTRT1 [SUTRT]		Electronic Cigarette(s)/E-Vapors

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

FORM STATUS CHANGE LOG

VISIT: Screening
FORM: Tobacco Use

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	16-Jul-2018 09:27 AM PDT (UTC-07:00)	Form marked as Complete
System	11-Jul-2018 10:55 AM PDT (UTC-07:00)	Form marked as Not Complete
System	11-Jul-2018 10:55 AM PDT (UTC-07:00)	Form marked as Complete
System	09-Jul-2018 08:40 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Screening
FORM: Tobacco Use

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Screening
FORM: Tobacco Use

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] SUYRUS1	NOT APPLICABLE [11-Jul-2018 10:56 AM by (b) (6) vinceandass	11-Jul-2018 10:55 AM	16-Jul-2018 09:27 AM

ID	Variable	Responses/Reasons	Opened	Closed
		ociates.com ([redacted] Response satisfies query [16-Jul-2018 09:27 AM by [redacted] vinceandassociates.com ([redacted] [redacted]		
	Description			
	New: Yearly Use is missing, please review **Old:** **By:** 11-Jul-2018 10:55 AM [redacted] vinceandassociates.com ([redacted]			
	[Row 1] SUWKUS1	NOT APPLICABLE [11-Jul-2018 10:56 AM by [redacted] vinceandassociates.com ([redacted] Response satisfies query [16-Jul-2018 09:27 AM by [redacted] vinceandassociates.com ([redacted] [redacted]	11-Jul-2018 10:55 AM	16-Jul-2018 09:27 AM
	Description			
	New: Weekly Use is missing, please review **Old:** **By:** 11-Jul-2018 10:55 AM [redacted] vinceandassociates.com ([redacted]			
	[Row 1] SUMONUS1	NOT APPLICABLE [11-Jul-2018 10:56 AM by [redacted] vinceandassociates.com ([redacted] Response satisfies query [16-Jul-2018 09:27 AM by [redacted] vinceandassociates.com ([redacted] [redacted]	11-Jul-2018 10:55 AM	16-Jul-2018 09:27 AM
	Description			
	New: Monthly Use is missing, please review			

ID	Variable	Responses/Reasons	Opened	Closed
	Old: **By:** 11-Jul-2018 10:55 AM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

VISIT: Screening
FORM: Tobacco Use

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

CLINICAL DATA

VISIT: Day -1
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day -1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:20 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		25-May-2018

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Visit Date

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

User	Date/Time	Change
System	31-May-2018 10:20 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day -1
FORM: Urine Pregnancy Test

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

Time Unknown: [LBTMNK]	

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Urine Pregnancy Test

User	Date/Time	Change
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Day -1
FORM: Urine Pregnancy Test

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

CLINICAL DATA

VISIT: Day -1
FORM: Vital Signs

Were vital signs measured? [VSPERF]	Yes
Repeat vital signs? [VSPERFR]	No
Time Seated: [VS1TIMS]	15:25
Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	25-May-2018
Time Taken: [VSTIM]	15:30
Time Unknown: [VSTMNK]	

Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.5
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	125
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	79
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	50
Unit: [VSORRESU]	beats/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 5	
Assessment: [VSTEST]	Respirations
Not done: [VSSTAT]	
Result: [VSORRES]	17
Unit: [VSORRESU]	breaths/min
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE

AUDIT TRAIL

VISIT: Day -1
FORM: Vital Signs

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:23 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
VSPERF [VSPERF]		Yes
VSPERFR [VSPERFR]		No
VSTIMS [VS1TIMS]		15:25
VS1DAT		25-May-2018

Variable	Old Value	New Value
[VSDAT]		
VSTIM [VSTIM]		15:30
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.5
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		125
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		79
[Row 3] VSORRESU [VSORRESU]		mmHg
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		50
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		17
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:23 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Vital Signs

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Vital Signs

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

CLINICAL DATA

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

Was the laboratory evaluation performed? [LBYN]	Yes

Date of collection: [LBDAT]	25-May-2018
Time of Collection: [LBTIM]	07:37
Time Unknown: [LBTMNK]	
Are all results within normal limits? [LBNRIND]	Yes

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:22 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
LBYN1 [LBYN]		Yes
LBDAT3 [LBDAT]		25-May-2018
LBTIM3 [LBTIM]		07:37
LBNRIND3 [LBNRIND]		Yes

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:22 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

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

AUDIT TRAIL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:22 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
PEYN2 [PEYN]		No

FORM STATUS CHANGE LOG

VISIT: Day -1
FORM: Symptom Directed Physical Exam

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:22 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day -1
FORM: Symptom Directed Physical Exam

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day -1
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

VISIT: Day 1
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 1
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:18 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN		Yes

Variable	Old Value	New Value
[SVYN]		
SVSTDAT [SVSTDAT]		26-May-2018

FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:18 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Visit Date

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

CLINICAL DATA

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

AD LIB USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG	
Date of Visit: [EXDAT]	26-May-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	10:59
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:04
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:26
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:33
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1

Time Dispensed: [EXTIM]	12:07
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:13
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:46
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:53
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:30
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:35
Row 6	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	14:12

Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	14:16
Row 7	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	14:39
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	14:42
Row 8	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	14:49
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	14:53

AUDIT TRAIL

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

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	07-Jun-2018 12:59 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		26-May-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM [EXTIM]		10:59
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		11:04
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1
[Row 2] EXTIM [EXTIM]		11:26
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		11:33
[Row 3] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		12:07
[Row 3] EXCIGRET [EXCIGRET]		1
[Row 3] EXTIMRET [EXTIMRET]		12:13
[Row 4] EXPRDT		Combustible Cigarette

Variable	Old Value	New Value
[EXPRDT]		
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		12:46
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		12:53
[Row 5] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD [EXDSPD]		1
[Row 5] EXTIM [EXTIM]		13:30
[Row 5] EXCIGRET [EXCIGRET]		1
[Row 5] EXTIMRET [EXTIMRET]		13:35
[Row 6] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD [EXDSPD]		1
[Row 6] EXTIM [EXTIM]		14:12
[Row 6] EXCIGRET [EXCIGRET]		1
[Row 6] EXTIMRET [EXTIMRET]		14:16
[Row 7] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD [EXDSPD]		1
[Row 7] EXTIM [EXTIM]		14:39
[Row 7] EXCIGRET [EXCIGRET]		1
[Row 7] EXTIMRET [EXTIMRET]		14:42
[Row 8] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 8] EXDSPD [EXDSPD]		1

Variable	Old Value	New Value
[Row 8] EXTIM [EXTIM]		14:49
[Row 8] EXCIGRET [EXCIGRET]		1
[Row 8] EXTIMRET [EXTIMRET]		14:53
Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	07-Jun-2018 07:56 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Database update	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]	26-May-2018	
[Row 1] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 1] EXDSPD [EXDSPD]	1	
[Row 1] EXTIM [EXTIM]	10:59	
[Row 1] EXCIGRET [EXCIGRET]	1	
[Row 1] EXTIMRET [EXTIMRET]	11:04	
[Row 2] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 2] EXDSPD [EXDSPD]	1	
[Row 2] EXTIM [EXTIM]	11:26	
[Row 2] EXCIGRET [EXCIGRET]	1	
[Row 2] EXTIMRET [EXTIMRET]	11:33	
[Row 3] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 3] EXDSPD [EXDSPD]	1	
[Row 3] EXTIM [EXTIM]	12:07	
[Row 3] EXCIGRET [EXCIGRET]	1	

Variable	Old Value	New Value
[Row 3] EXTIMRET [EXTIMRET]	12:13	
[Row 4] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 4] EXDSPD [EXDSPD]	1	
[Row 4] EXTIM [EXTIM]	12:46	
[Row 4] EXCIGRET [EXCIGRET]	1	
[Row 4] EXTIMRET [EXTIMRET]	12:53	
[Row 5] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 5] EXDSPD [EXDSPD]	1	
[Row 5] EXTIM [EXTIM]	13:30	
[Row 5] EXCIGRET [EXCIGRET]	1	
[Row 5] EXTIMRET [EXTIMRET]	13:35	
[Row 6] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 6] EXDSPD [EXDSPD]	1	
[Row 6] EXTIM [EXTIM]	14:12	
[Row 6] EXCIGRET [EXCIGRET]	1	
[Row 6] EXTIMRET [EXTIMRET]	14:16	
[Row 7] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 7] EXDSPD [EXDSPD]	1	
[Row 7] EXTIM [EXTIM]	14:39	
[Row 7] EXCIGRET [EXCIGRET]	1	
[Row 7] EXTIMRET [EXTIMRET]	14:42	

Variable	Old Value	New Value
[Row 8] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 8] EXDSPD [EXDSPD]	1	
[Row 8] EXTIM [EXTIM]	14:49	
[Row 8] EXCIGRET [EXCIGRET]	1	
[Row 8] EXTIMRET [EXTIMRET]	14:53	
[Row 9] EXPRDT [EXPRDT]	Combustible Cigarette	
[Row 10] EXPRDT [EXPRDT]	Combustible Cigarette	
Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	05-Jun-2018 12:55 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT [EXDAT]		26-May-2018
[Row 1] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD [EXDSPD]		1
[Row 1] EXTIM [EXTIM]		10:59
[Row 1] EXCIGRET [EXCIGRET]		1
[Row 1] EXTIMRET [EXTIMRET]		11:04
[Row 2] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD [EXDSPD]		1
[Row 2] EXTIM [EXTIM]		11:26
[Row 2] EXCIGRET [EXCIGRET]		1
[Row 2] EXTIMRET [EXTIMRET]		11:33
[Row 3] EXPRDT		Combustible Cigarette

Variable	Old Value	New Value
[EXPRDT]		
[Row 3] EXDSPD [EXDSPD]		1
[Row 3] EXTIM [EXTIM]		12:07
[Row 3] EXCIGRET [EXCIGRET]		1
[Row 3] EXTIMRET [EXTIMRET]		12:13
[Row 4] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD [EXDSPD]		1
[Row 4] EXTIM [EXTIM]		12:46
[Row 4] EXCIGRET [EXCIGRET]		1
[Row 4] EXTIMRET [EXTIMRET]		12:53
[Row 5] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD [EXDSPD]		1
[Row 5] EXTIM [EXTIM]		13:30
[Row 5] EXCIGRET [EXCIGRET]		1
[Row 5] EXTIMRET [EXTIMRET]		13:35
[Row 6] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 6] EXDSPD [EXDSPD]		1
[Row 6] EXTIM [EXTIM]		14:12
[Row 6] EXCIGRET [EXCIGRET]		1
[Row 6] EXTIMRET [EXTIMRET]		14:16
[Row 7] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 7] EXDSPD [EXDSPD]		1

Variable	Old Value	New Value
[Row 7] EXTIM [EXTIM]		14:39
[Row 7] EXCIGRET [EXCIGRET]		1
[Row 7] EXTIMRET [EXTIMRET]		14:42
[Row 8] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 8] EXDSPD [EXDSPD]		1
[Row 8] EXTIM [EXTIM]		14:49
[Row 8] EXCIGRET [EXCIGRET]		1
[Row 8] EXTIMRET [EXTIMRET]		14:53
[Row 9] EXPRDT [EXPRDT]		Combustible Cigarette
[Row 10] EXPRDT [EXPRDT]		Combustible Cigarette

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	07-Jun-2018 12:59 PM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 12:55 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 12:55 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FIELD STATUSES

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

Variable	Row Number	User	Date/Time	Field status
EXPRDT	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXPRDT	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared

Variable	Row Number	User	Date/Time	Field status
EXDSPD	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDSPD	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared

Variable	Row Number	User	Date/Time	Field status
EXTIM	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIM	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXCIGRET	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	10	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared

Variable	Row Number	User	Date/Time	Field status
EXTIMRET	9	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	8	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	7	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	6	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	5	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	4	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	3	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	2	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXTIMRET	1	(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared
EXDAT		(b) (6) vincean dassociates.com (b) (6) (b) (6)	07-Jun-2018 07:56 AM PDT (UTC-07:00)	The status was set to Cleared

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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	02-Aug-2018 11:50 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

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

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 10] EXTIMRET	Invalidated by clearing the form [07-Jun-2018 07:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM
	Description			
	New: Time Returned is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM (b) (6) vinceandassociates.com (b) (6)			
	[Row 9] EXTIMRET	Invalidated by clearing the form [07-Jun-2018 07:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM
	Description			
	New: Time Returned is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM (b) (6) vinceandassociates.com (b) (6)			
	[Row 10] EXTIM	Invalidated by clearing the form [07-Jun-2018 07:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM
	Description			
	New: Time Dispenses is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM (b) (6) vinceandassociates.com (b) (6)			

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 9] EXTIM	Invalidated by clearing the form [07-Jun-2018 07:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM
	Description			
	New: Time Dispenses is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM (b) (6) vinceandassociates.com (b) (6)			
	[Row 10] EXCIGRET	Invalidated by clearing the form [07-Jun-2018 07:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM
	Description			
	New: Number of Butts returned is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM (b) (6) vinceandassociates.com (b) (6)			
	[Row 9] EXCIGRET	Invalidated by clearing the form [07-Jun-2018 07:56 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6)	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM
	Description			
	New: Number of Butts returned is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM (b) (6) vinceandassociates.com (b) (6)			
	[Row 10] EXDSPD	Invalidated by clearing the form [07-Jun-2018 07:56 AM by (b) (6) vinceanda	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM

ID	Variable	Responses/Reasons	Opened	Closed
		ssociates.com ([redacted] [redacted]		
	Description			
	New: Number dispensed is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM [redacted] vinceandassociates.com ([redacted]			
	[Row 9] EXDSPD	Invalidated by clearing the form [07-Jun-2018 07:56 AM by [redacted] vinceanda ssociates.com ([redacted] [redacted]	05-Jun-2018 12:55 PM	07-Jun-2018 07:56 AM
	Description			
	New: Number dispensed is missing, please review **Old:** **By:** 05-Jun-2018 12:55 PM [redacted] vinceandassociates.com ([redacted]			

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			[redacted] algo pharm.com ([redacted] [redacted]	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
(b) (6) vinceandassociates.com ((b) (6)	05-Jun-2018 12:55 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Date of Visit: [EXDAT]	
Row 1	
Product Used: [EXPRDT]	
Number Dispensed: [EXDSPD]	
Time Dispensed: [EXTIM]	
Number of Pieces Returned: [EXNICRET]	
Time Returned/Discarded: [EXTIMRET]	

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	05-Jun-2018 12:55 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 1
FORM: Randomization

Date of Randomization: [DSRDAT]	26-May-2018
Randomization Number: [DSNUM]	1030
Sequence Group [DSRNGRP]	BCA

AUDIT TRAIL

VISIT: Day 1
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 12:57 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]		BCA
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:19 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		26-May-2018
DSRNUM [DSNUM]		1030

FORM STATUS CHANGE LOG

VISIT: Day 1
FORM: Randomization

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:19 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Randomization

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Randomization

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

CLINICAL DATA

VISIT: Day 1
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 1
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 06:46 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 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	06-Jun-2018 06:46 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 1
FORM: Use Product Again - VAS

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 1
FORM: Use Product Again - VAS

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

CLINICAL DATA

VISIT: Day 2
FORM: Visit Date

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

AUDIT TRAIL

VISIT: Day 2
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:17 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		27-May-2018

FORM STATUS CHANGE LOG

VISIT: Day 2
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:17 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	29-May-2018 11:41 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Day 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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	29-May-2018 11:41 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Day 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]	27-May-2018

Row 1	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:00
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	11:03
Row 2	
Product Used: [EXPRDT]	Nicorette Original Flavor Gum (4 mg)
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:41
Number of Pieces Returned: [EXNICRET]	1
Time Returned/Discarded: [EXTIMRET]	11:43

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:01 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT2 [EXDAT]		27-May-2018
[Row 1] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)

Variable	Old Value	New Value
[Row 1] EXDSPD2 [EXDSPD]		1
[Row 1] EXTIM2 [EXTIM]		11:00
[Row 1] EXNICRET [EXNICRET]		1
[Row 1] EXTIMRET2 [EXTIMRET]		11:03
[Row 2] EXPRDT2 [EXPRDT]		Nicorette Original Flavor Gum (4 mg)
[Row 2] EXDSPD2 [EXDSPD]		1
[Row 2] EXTIM2 [EXTIM]		11:41
[Row 2] EXNICRET [EXNICRET]		1
[Row 2] EXTIMRET2 [EXTIMRET]		11:43

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	07-Jun-2018 01:01 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 12:57 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	29-May-2018 11:41 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 11:50 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 2
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 2
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 06:46 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 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	06-Jun-2018 06:46 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 2
FORM: Use Product Again - VAS

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 2
FORM: Use Product Again - VAS

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

CLINICAL DATA

VISIT: Day 3
FORM: Visit Date

Visit Done? [SVYN]	Yes

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

AUDIT TRAIL

VISIT: Day 3
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:16 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		28-May-2018

FORM STATUS CHANGE LOG

VISIT: Day 3
FORM: Visit Date

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:16 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
FORM: Visit Date

User	**Date/Time**	**Status**
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 3
FORM: Visit Date

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

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

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

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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]	28-May-2018
Row 1	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	11:00
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:03
Row 2	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1

Time Dispensed: [EXTIM]	11:22
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	11:26
Row 3	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	12:09
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	12:14
Row 4	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	13:39
Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	13:43
Row 5	
Product Used: [EXPRDT]	Combustible Cigarette
Number Dispensed: [EXDSPD]	1
Time Dispensed: [EXTIM]	14:08

Number of Butts Returned: [EXCIGRET]	1
Time Returned: [EXTIMRET]	14:12

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:04 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Updated information	
Variable	**Old Value**	**New Value**
[Row 6] EXPRDT1 [EXPRDT]	Combustible Cigarette	
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:03 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDAT1 [EXDAT]		28-May-2018
[Row 1] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 1] EXDSPD1 [EXDSPD]		1
[Row 1] EXTIM1 [EXTIM]		11:00
[Row 1] EXCIGRET1 [EXCIGRET]		1
[Row 1] EXTIMRET1 [EXTIMRET]		11:03
[Row 2] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 2] EXDSPD1 [EXDSPD]		1
[Row 2] EXTIM1 [EXTIM]		11:22

Variable	Old Value	New Value
[Row 2] EXCIGRET1 [EXCIGRET]		1
[Row 2] EXTIMRET1 [EXTIMRET]		11:26
[Row 3] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 3] EXDSPD1 [EXDSPD]		1
[Row 3] EXTIM1 [EXTIM]		12:09
[Row 3] EXCIGRET1 [EXCIGRET]		1
[Row 3] EXTIMRET1 [EXTIMRET]		12:14
[Row 4] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 4] EXDSPD1 [EXDSPD]		1
[Row 4] EXTIM1 [EXTIM]		13:39
[Row 4] EXCIGRET1 [EXCIGRET]		1
[Row 4] EXTIMRET1 [EXTIMRET]		13:43
[Row 5] EXPRDT1 [EXPRDT]		Combustible Cigarette
[Row 5] EXDSPD1 [EXDSPD]		1
[Row 5] EXTIM1 [EXTIM]		14:08
[Row 5] EXCIGRET1 [EXCIGRET]		1
[Row 5] EXTIMRET1 [EXTIMRET]		14:12
[Row 6] EXPRDT1 [EXPRDT]		Combustible Cigarette

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	07-Jun-2018 01:04 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 12:57 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	29-May-2018 11:41 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 11:51 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

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

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 6] EXTIM1	Data Updated [07-Jun-2018 01:04 PM by (b) (6) vinceandassociates.com ((b) (6)	07-Jun-2018 01:03 PM	07-Jun-2018 01:04 PM
	Description			
	New: Time is missing, please review **Old:** **By:** 07-Jun-2018 01:03 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 6] EXCIGRET1	Data Updated [07-Jun-2018 01:04 PM by (b) (6) vinceandassociates.com ((b) (6)	07-Jun-2018 01:03 PM	07-Jun-2018 01:04 PM
	Description			
	New: Number of Butts Returned is missing, please review **Old:** **By:** 07-Jun-2018 01:03 PM (b) (6) vinceandassociates.com ((b) (6)			
	[Row 6] EXDSPD1	Data Updated [07-Jun-2018 01:04 PM by (b) (6) vinceandassociates.com ((b) (6)	07-Jun-2018 01:03 PM	07-Jun-2018 01:04 PM
	Description			
	New: Number Dispensed is missing, please review **Old:** **By:** 07-Jun-2018 01:03 PM (b) (6) vinceandassociates.com ((b) (6)			

LOCKING HISTORY

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

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

CLINICAL DATA

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

AD LIB NICORETTE ORIGINAL FLAVOR GUM (4 MG) PRODUCT USE LOG	
Date of Visit: [EXDAT]	
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	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected

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

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 3
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 3
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 06:47 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 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	06-Jun-2018 06:47 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 3
FORM: Use Product Again - VAS

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 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) algopharm.com ((b) (6) (b) (6)	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Unlocked	Locked

CLINICAL DATA

VISIT: Day 4
FORM: Visit Date

Visit Done? [SVYN]	Yes

Date of Visit: [SVSTDAT]	29-May-2018

AUDIT TRAIL

VISIT: Day 4
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6)	
Date/Time	31-May-2018 10:14 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		29-May-2018

FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Visit Date

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:14 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
FORM: Visit Date

User	**Date/Time**	**Status**
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 4
FORM: Visit Date

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

CLINICAL DATA

VISIT: Day 4
FORM: Randomization

Date of Randomization: [DSRDAT]	29-May-2018
Randomization Number: [DSNUM]	2030
Sequence Group [DSRNGRP]	BCA

AUDIT TRAIL

VISIT: Day 4
FORM: Randomization

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:04 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]		BCA
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:14 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
DSRNDAT [DSRDAT]		29-May-2018
DSRNUM [DSNUM]		2030

FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Randomization

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:14 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 4
FORM: Randomization

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 4
FORM: Randomization

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

CLINICAL DATA

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

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

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

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

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

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

LOCKING HISTORY

VISIT: Day 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]	29-May-2018
Session Start Time: [EXSRTTIM]	17:00
Session End Time: [EXENDTIM]	17:04
Row 1	
Inhalation Begin: [EXINHBG]	17:00:01
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:03

Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	17:00:11
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:14
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	17:00:27
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:29
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	17:00:58
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:59
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	17:01:17
Time Unknown: [EXTIMUNK]	

Inhalation End: [EXINEN]	17:01:19
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	17:01:40
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:01:42
Time Unknown: [EXTIMUNK]	
Row 7	
Inhalation Begin: [EXINHBG]	17:02:15
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:02:17
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	17:02:51
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:02:52
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	17:03:10

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:03:11
Time Unknown: [EXTIMUNK]	
Row 10	
Inhalation Begin: [EXINHBG]	17:03:37
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:03:38
Time Unknown: [EXTIMUNK]	
Row 11	
Inhalation Begin: [EXINHBG]	17:04:23
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:04:24
Time Unknown: [EXTIMUNK]	
Row 12	
Inhalation Begin: [EXINHBG]	17:04:33
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:04:34
Time Unknown: [EXTIMUNK]	

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:09 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATB [EXDATB]		29-May-2018
EXSRTTIM [EXSRTTIM]		17:00
EXENDTIM [EXENDTIM]		17:04
[Row 1] EXINHBG [EXINHBG]		17:00:01
[Row 1] EXINEN [EXINEN]		17:00:03
[Row 2] EXINHBG [EXINHBG]		17:00:11
[Row 2] EXINEN [EXINEN]		17:00:14
[Row 3] EXINHBG [EXINHBG]		17:00:27
[Row 3] EXINEN [EXINEN]		17:00:29
[Row 4] EXINHBG [EXINHBG]		17:00:58
[Row 4] EXINEN [EXINEN]		17:00:59
[Row 5] EXINHBG [EXINHBG]		17:01:17
[Row 5] EXINEN [EXINEN]		17:01:19
[Row 6] EXINHBG [EXINHBG]		17:01:40

Variable	Old Value	New Value
[Row 6] EXINEN [EXINEN]		17:01:42
[Row 7] EXINHBG [EXINHBG]		17:02:15
[Row 7] EXINEN [EXINEN]		17:02:17
[Row 8] EXINHBG [EXINHBG]		17:02:51
[Row 8] EXINEN [EXINEN]		17:02:52
[Row 9] EXINHBG [EXINHBG]		17:03:10
[Row 9] EXINEN [EXINEN]		17:03:11
[Row 10] EXINHBG [EXINHBG]		17:03:37
[Row 10] EXINEN [EXINEN]		17:03:38
[Row 11] EXINHBG [EXINHBG]		17:04:23
[Row 11] EXINEN [EXINEN]		17:04:24
[Row 12] EXINHBG [EXINHBG]		17:04:33
[Row 12] EXINEN [EXINEN]		17:04:34
EXBEVB [EXBEVB]		No
EXINTOT [EXINTOT]		12

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 01:09 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:04 PM PDT (UTC-07:00)	Form marked as Not Complete

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

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 11:53 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED USUAL BRAND (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	29-May-2018

Session Start Time: [EXSTTIM]	11:00
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	11:00:00
Puff End: [EXPFEN]	11:00:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2
Puff Begin: [EXPFBG]	11:00:30
Puff End: [EXPFEN]	11:00:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	11:01:00
Puff End: [EXPFEN]	11:01:03
Missed Puff: [EXMISPF]	No

If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	11:01:30
Puff End: [EXPFEN]	11:01:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	11:02:00
Puff End: [EXPFEN]	11:02:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	11:02:30
Puff End: [EXPFEN]	11:02:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	11:03:00
Puff End: [EXPFEN]	11:03:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	11:03:30
Puff End: [EXPFEN]	11:03:32
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 9	
Puff: [EXPFF]	Puff 9
Puff Begin: [EXPFBG]	11:04:00
Puff End: [EXPFEN]	11:04:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:06 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX8DATVLN [EXDATVLN]		29-May-2018
EX8STTIM [EXSTTIM]		11:00
[Row 1] EX8PFF [EXPFF]		Puff 1
[Row 1] EX8PFBG [EXPFBG]		11:00:00
[Row 1] EX8PFEN [EXPFEN]		11:00:03
[Row 1] EX8MISPF [EXMISPF]		No
[Row 2] EX8PFF [EXPFF]		Puff 2
[Row 2] EX8PFBG		11:00:30

Variable	Old Value	New Value
[EXPFBG]		
[Row 2] EX8PFEN [EXPFEN]		11:00:33
[Row 2] EX8MISPF [EXMISPF]		No
[Row 3] EX8PFF [EXPFF]		Puff 3
[Row 3] EX8PFBG [EXPFBG]		11:01:00
[Row 3] EX8PFEN [EXPFEN]		11:01:03
[Row 3] EX8MISPF [EXMISPF]		No
[Row 4] EX8PFF [EXPFF]		Puff 4
[Row 4] EX8PFBG [EXPFBG]		11:01:30
[Row 4] EX8PFEN [EXPFEN]		11:01:33
[Row 4] EX8MISPF [EXMISPF]		No
[Row 5] EX8PFF [EXPFF]		Puff 5
[Row 5] EX8PFBG [EXPFBG]		11:02:00
[Row 5] EX8PFEN [EXPFEN]		11:02:03
[Row 5] EX8MISPF [EXMISPF]		No
[Row 6] EX8PFF [EXPFF]		Puff 6
[Row 6] EX8PFBG [EXPFBG]		11:02:30
[Row 6] EX8PFEN [EXPFEN]		11:02:33
[Row 6] EX8MISPF [EXMISPF]		No
[Row 7] EX8PFF [EXPFF]		Puff 7
[Row 7] EX8PFBG [EXPFBG]		11:03:00
[Row 7] EX8PFEN [EXPFEN]		11:03:03

Variable	Old Value	New Value
[Row 7] EX8MISPF [EXMISPF]		No
[Row 8] EX8PFF [EXPFF]		Puff 8
[Row 8] EX8PFBG [EXPFBG]		11:03:30
[Row 8] EX8PFEN [EXPFEN]		11:03:32
[Row 8] EX8MISPF [EXMISPF]		No
[Row 9] EX8PFF [EXPFF]		Puff 9
[Row 9] EX8PFBG [EXPFBG]		11:04:00
[Row 9] EX8PFEN [EXPFEN]		11:04:03
[Row 9] EX8MISPF [EXMISPF]		No
[Row 10] EX8PFF [EXPFF]		Puff 10
[Row 10] EX8PFBG [EXPFBG]		11:04:30
[Row 10] EX8PFEN [EXPFEN]		11:04:33
[Row 10] EX8MISPF [EXMISPF]		No
EX8BEVB [EXBEVB]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 01:06 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:04 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected

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

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	02-Aug-2018 11:52 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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 VLN Dosing Log

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

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

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

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

FORM STATUS CHANGE LOG

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

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 06:49 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF		Yes

Variable	Old Value	New Value
[QSPERF]		
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	06-Jun-2018 06:49 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 06:49 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 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	06-Jun-2018 06:49 AM PDT (UTC-07:00)	Form marked as Complete

User	Date/Time	Change
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Completed: [QSYN]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 06:49 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 4
FORM: 1st Use - Direct Effects of Product Questionnaire

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 06:49 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 06:50 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF2		Yes

Variable	Old Value	New Value
[QSPERF]		
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	06-Jun-2018 06:50 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	10:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:06
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:16
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:20

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	11:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	12:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	12:32
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	13:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	13:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	14:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) [redacted] vinceandassociates.com (b) (6) (b) (6) (b) (6)
Date/Time	06-Jun-2018 06:55 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]		29-May-2018
[Row 1] PKTIM [PKTIM]		10:55
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		29-May-2018
[Row 2] PKTIM [PKTIM]		11:02
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		29-May-2018
[Row 3] PKTIM [PKTIM]		11:06
[Row 3] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		29-May-2018
[Row 4] PKTIM [PKTIM]		11:07
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		29-May-2018
[Row 5] PKTIM [PKTIM]		11:10
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		29-May-2018
[Row 6] PKTIM [PKTIM]		11:12

Variable	Old Value	New Value
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		29-May-2018
[Row 7] PKTIM [PKTIM]		11:16
[Row 7] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		29-May-2018
[Row 8] PKTIM [PKTIM]		11:20
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		29-May-2018
[Row 9] PKTIM [PKTIM]		11:30
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		29-May-2018
[Row 10] PKTIM [PKTIM]		11:45
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		29-May-2018
[Row 11] PKTIM [PKTIM]		12:00
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		29-May-2018
[Row 12] PKTIM [PKTIM]		12:32
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute

Variable	Old Value	New Value
[Row 13] PKDAT [PKDAT]		29-May-2018
[Row 13] PKTIM [PKTIM]		13:00
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		29-May-2018
[Row 14] PKTIM [PKTIM]		13:30
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		29-May-2018
[Row 15] PKTIM [PKTIM]		14:00

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 06:55 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	16:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:02

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:06
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:16
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	B - Late due to previous procedure
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	17:45

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	18:01
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	18:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute

Date: [PKDAT]	29-May-2018
Time: [PKTIM]	19:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	19:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	29-May-2018
Time: [PKTIM]	20:00
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) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:03 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]		29-May-2018
[Row 1] PKTIM1 [PKTIM]		16:55
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		29-May-2018
[Row 2] PKTIM1 [PKTIM]		17:02
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		29-May-2018
[Row 3] PKTIM1 [PKTIM]		17:06
[Row 3] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		29-May-2018
[Row 4] PKTIM1 [PKTIM]		17:07
[Row 5] PKTPT1		10 minute

Variable	Old Value	New Value
[PKTPT]		
[Row 5] PKDAT1 [PKDAT]		29-May-2018
[Row 5] PKTIM1 [PKTIM]		17:10
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		29-May-2018
[Row 6] PKTIM1 [PKTIM]		17:12
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		29-May-2018
[Row 7] PKTIM1 [PKTIM]		17:16
[Row 7] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		29-May-2018
[Row 8] PKTIM1 [PKTIM]		17:20
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		29-May-2018
[Row 9] PKTIM1 [PKTIM]		17:30
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		29-May-2018
[Row 10] PKTIM1 [PKTIM]		17:45
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		29-May-2018
[Row 11] PKTIM1 [PKTIM]		18:01

Variable	Old Value	New Value
[Row 11] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		29-May-2018
[Row 12] PKTIM1 [PKTIM]		18:30
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		29-May-2018
[Row 13] PKTIM1 [PKTIM]		19:00
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		29-May-2018
[Row 14] PKTIM1 [PKTIM]		19:30
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		29-May-2018
[Row 15] PKTIM1 [PKTIM]		20:00

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	06-Jun-2018 07:03 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 4
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 4
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jun-2018 10:10 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
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:09 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]	Yes	
QS5USE [QSUSE]	1st Use	
Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:05 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 4
FORM: Use Product Again - VAS

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	12-Jun-2018 10:10 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:09 PM PDT (UTC-07:00)	Form marked as Not Complete
System	06-Jun-2018 07:05 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FIELD STATUSES

VISIT: Day 4
FORM: Use Product Again - VAS

Variable	Row Number	User	Date/Time	Field status
QS5PERF		(b) (6) vinceandassociates.com (b) (6)	07-Jun-2018 01:09 PM PDT (UTC-07:00)	The status was set to Cleared
QS5USE		(b) (6) vinceandassociates.com (b) (6)	07-Jun-2018 01:09 PM PDT (UTC-07:00)	The status was set to Cleared

FORM APPROVAL

VISIT: Day 4
FORM: Use Product Again - VAS

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 4
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 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	12-Jun-2018 10:10 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jun-2018 10:10 AM PDT (UTC-07:00)	Form marked as Complete

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

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 5
FORM: Visit Date

Visit Done? [SVYN]	Yes
Date of Visit: [SVSTDAT]	30-May-2018

AUDIT TRAIL

VISIT: Day 5
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	31-May-2018 10:14 AM PDT (UTC-07:00)	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		30-May-2018

FORM STATUS CHANGE LOG

VISIT: Day 5
FORM: Visit Date

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	31-May-2018 10:14 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 5
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 5
FORM: Visit Date

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

CLINICAL DATA

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

CONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	30-May-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	11:00
Session End Time: [EXENTMB]	11:10
Did the subject consume any beverages during controlled product use?: [EXBEV]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	07-Jun-2018 01:11 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT [EXNICDAT]		30-May-2018
[Row 1] EXPRDB [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB [EXSRTTIMB]		11:00
[Row 1] EXENTMB [EXENTMB]		11:10
EXBEV [EXBEV]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 01:11 PM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 11:53 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED NICORETTE ORIGINAL FLAVOR GUM (4 mg) PRODUCT USE LOG (Subject to use one unit of product ad libitum for 10 minutes)	
Date of Visit: [EXNICDAT]	30-May-2018
Row 1	
Product: [EXPRDB]	Nicorette Original Flavor Gum (4 mg)
Session Start Time: [EXSRTTIMB]	17:00
Session End Time: [EXENTMB]	17:00
Did the subject consume any beverages during controlled product use?: [EXBEV]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	07-Jun-2018 01:11 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXNICDAT2 [EXNICDAT]		30-May-2018
[Row 1] EXPRDB2 [EXPRDB]		Nicorette Original Flavor Gum (4 mg)
[Row 1] EXSRTTIMB2 [EXSRTTIMB]		17:00
[Row 1] EXENTMB2 [EXENTMB]		17:00
EXBEV2 [EXBEV]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 01:11 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:04 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 11:54 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

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

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

FORM STATUS CHANGE LOG

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

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

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

LOCKING HISTORY

VISIT: Day 5
FORM: Part B - Controlled 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]	
Session Start Time: [EXSRTTIM]	
Session End Time: [EXENDTIM]	
Row 1	
Inhalation Begin: [EXINHBG]	
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	

Time Unknown: [EXTIMUNK]	

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:06 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	06-Jun-2018 07:06 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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".

User	Date/Time	Status
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 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) 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 - Tobacco/Nicotine Questionnaire

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:07 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	06-Jun-2018 07:07 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:07 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	06-Jun-2018 07:07 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Use: [QSUSE]	2nd Use
Row 1	
Time point: [QSTMPT]	
Completed: [QSYN]	

AUDIT TRAIL

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

Logged in User	[redacted] vinceandassociates.com ([redacted]) [redacted]	
Date/Time	06-Jun-2018 07:07 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	06-Jun-2018 07:07 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	10:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:31

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	11:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	12:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute

Date: [PKDAT]	30-May-2018
Time: [PKTIM]	12:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	13:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	13:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	14:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:12 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]		30-May-2018
[Row 1] PKTIM [PKTIM]		10:55
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		30-May-2018

Variable	Old Value	New Value
[Row 2] PKTIM [PKTIM]		11:02
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		30-May-2018
[Row 3] PKTIM [PKTIM]		11:05
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		30-May-2018
[Row 4] PKTIM [PKTIM]		11:07
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		30-May-2018
[Row 5] PKTIM [PKTIM]		11:10
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		30-May-2018
[Row 6] PKTIM [PKTIM]		11:12
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		30-May-2018
[Row 7] PKTIM [PKTIM]		11:15
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		30-May-2018
[Row 8] PKTIM [PKTIM]		11:20
[Row 9] PKTPT [PKTPT]		30 minute
[Row 9] PKDAT [PKDAT]		30-May-2018

Variable	Old Value	New Value
[Row 9] PKTIM [PKTIM]		11:31
[Row 9] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		30-May-2018
[Row 10] PKTIM [PKTIM]		11:45
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		30-May-2018
[Row 11] PKTIM [PKTIM]		12:00
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		30-May-2018
[Row 12] PKTIM [PKTIM]		12:30
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		30-May-2018
[Row 13] PKTIM [PKTIM]		13:00
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		30-May-2018
[Row 14] PKTIM [PKTIM]		13:30
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		30-May-2018
[Row 15] PKTIM [PKTIM]		14:00

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	06-Jun-2018 07:12 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	16:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:05

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute

Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:31
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	17:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	18:00

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	18:31
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	19:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute

Date: [PKDAT]	30-May-2018
Time: [PKTIM]	19:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	30-May-2018
Time: [PKTIM]	20:00
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) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:17 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		Predose

Variable	Old Value	New Value
[PKTPT]		
[Row 1] PKDAT1 [PKDAT]		30-May-2018
[Row 1] PKTIM1 [PKTIM]		16:55
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		30-May-2018
[Row 2] PKTIM1 [PKTIM]		17:02
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		30-May-2018
[Row 3] PKTIM1 [PKTIM]		17:05
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		30-May-2018
[Row 4] PKTIM1 [PKTIM]		17:07
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		30-May-2018
[Row 5] PKTIM1 [PKTIM]		17:10
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		30-May-2018
[Row 6] PKTIM1 [PKTIM]		17:12
[Row 7] PKTPT1 [PKTPT]		15 minute
[Row 7] PKDAT1 [PKDAT]		30-May-2018
[Row 7] PKTIM1 [PKTIM]		17:15
[Row 8] PKTPT1 [PKTPT]		20 minute

Variable	Old Value	New Value
[Row 8] PKDAT1 [PKDAT]		30-May-2018
[Row 8] PKTIM1 [PKTIM]		17:20
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		30-May-2018
[Row 9] PKTIM1 [PKTIM]		17:31
[Row 9] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		30-May-2018
[Row 10] PKTIM1 [PKTIM]		17:45
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		30-May-2018
[Row 11] PKTIM1 [PKTIM]		18:00
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		30-May-2018
[Row 12] PKTIM1 [PKTIM]		18:31
[Row 12] PKCODE1 [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		30-May-2018
[Row 13] PKTIM1 [PKTIM]		19:00
[Row 14] PKTPT1 [PKTPT]		150 minute
[Row 14] PKDAT1 [PKDAT]		30-May-2018

Variable	Old Value	New Value
[Row 14] PKTIM1 [PKTIM]		19:30
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		30-May-2018
[Row 15] PKTIM1 [PKTIM]		20:00

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	06-Jun-2018 07:17 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 5
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 5
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jun-2018 10:11 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
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:10 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]	Yes	

Variable	Old Value	New Value
QS5USE [QSUSE]	1st Use	
Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:17 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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jun-2018 10:11 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:10 PM PDT (UTC-07:00)	Form marked as Not Complete
System	06-Jun-2018 07:17 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FIELD STATUSES

VISIT: Day 5
FORM: Use Product Again - VAS

Variable	Row Number	User	Date/Time	Field status
QS5PERF		(b) (6) vinceandassociates.com (b) (6)	07-Jun-2018 01:10 PM PDT (UTC-07:00)	The status was set to Cleared
QS5USE		(b) (6) vinceandassociates.com (b) (6)	07-Jun-2018 01:10 PM PDT (UTC-07:00)	The status was set to Cleared

FORM APPROVAL

VISIT: Day 5
FORM: Use Product Again - VAS

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:51 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 5
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 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	12-Jun-2018 10:11 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jun-2018 10:11 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	07-Aug-2018 12:51 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]	31-May-2018

AUDIT TRAIL

VISIT: Day 6
FORM: Visit Date

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:17 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
SVYN [SVYN]		Yes
SVSTDAT [SVSTDAT]		31-May-2018

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Visit Date

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

User	Date/Time	Change
System	06-Jun-2018 07:17 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Visit Date

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 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]	20:10

Time Seated Unknown: [VSTIMSUN]	
Date: [VSDAT]	31-May-2018
Time Taken: [VSTIM]	20:15
Time Unknown: [VSTMNK]	
Row 1	
Assessment: [VSTEST]	Oral Temperature
Not done: [VSSTAT]	
Result: [VSORRES]	36.9
Unit: [VSORRESU]	C
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 2	
Assessment: [VSTEST]	Systolic Blood Pressure
Not done: [VSSTAT]	
Result: [VSORRES]	138
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 3	
Assessment: [VSTEST]	Diastolic Blood Pressure

Not done: [VSSTAT]	
Result: [VSORRES]	93
Unit: [VSORRESU]	mmHg
MD Safety Review: [VSCLSIG]	WITHIN NORMAL RANGE
Row 4	
Assessment: [VSTEST]	Pulse Rate
Not done: [VSSTAT]	
Result: [VSORRES]	61
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) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:24 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]		20:10
VS1DAT [VSDAT]		31-May-2018
VSTIM [VSTIM]		20:15
[Row 1] VSTEST [VSTEST]		Oral Temperature
[Row 1] VSORRES [VSORRES]		36.9
[Row 1] VSORRESU [VSORRESU]		C
[Row 1] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 2] VSTEST [VSTEST]		Systolic Blood Pressure
[Row 2] VSORRES [VSORRES]		138
[Row 2] VSORRESU [VSORRESU]		mmHg
[Row 2] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 3] VSTEST [VSTEST]		Diastolic Blood Pressure
[Row 3] VSORRES [VSORRES]		93
[Row 3] VSORRESU [VSORRESU]		mmHg

Variable	Old Value	New Value
[Row 3] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 4] VSTEST [VSTEST]		Pulse Rate
[Row 4] VSORRES [VSORRES]		61
[Row 4] VSORRESU [VSORRESU]		beats/min
[Row 4] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE
[Row 5] VSTEST [VSTEST]		Respirations
[Row 5] VSORRES [VSORRES]		14
[Row 5] VSORRESU [VSORRESU]		breaths/min
[Row 5] VSCLSIG [VSCLSIG]		WITHIN NORMAL RANGE

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Vital Signs

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:24 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Vital Signs

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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Day 6
FORM: Chemistry Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	31-May-2018
Time of Collection: [LBTIM]	20:00
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: Day 6
FORM: Chemistry Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:24 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN2 [LBYN]		Yes
LBDAT5 [LBDAT]		31-May-2018
LBTIM5 [LBTIM]		20:00
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	06-Jun-2018 07:24 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 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) 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: Hematology Laboratory Evaluation

Was the laboratory evaluation performed? [LBYN]	Yes
Date of collection: [LBDAT]	31-May-2018
Time of Collection: [LBTIM]	20:00
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: Day 6
FORM: Hematology Laboratory Evaluation

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:24 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN6 [LBYN]		Yes
LBDAT6 [LBDAT]		31-May-2018
LBTIM6 [LBTIM]		20:00
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	06-Jun-2018 07:24 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 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]	31-May-2018
Time of Collection: [LBTIM]	06:26
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) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:25 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
LBYN3 [LBYN]		Yes
LBDAT7 [LBDAT]		31-May-2018
LBTIM7 [LBTIM]		06:26
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	06-Jun-2018 07:25 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:59 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]	No
Examination Date: [PEDAT]	
Completion Time: [PTIM]	
ABBREVIATED (SYMPTOM-DIRECTED) PHYSICAL EXAM	
Row 1	
Body System Examined: [PETEST]	
Not done: [PESTAT]	
Examination Results: [PEORRES]	
Abnormal Findings: [PECLSIG]	
If Other, please specify: [PEOTHSP]	

AUDIT TRAIL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:25 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PEYN2 [PEYN]		No

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Symptom Directed Physical Exam

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:25 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: Symptom Directed Physical Exam

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: Symptom Directed Physical Exam

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

CLINICAL DATA

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

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

FORM STATUS CHANGE LOG

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

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

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

LOCKING HISTORY

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

Item type	Item	Row Number	User	Date/Time	Old Value	New Value
Form			(b) (6) 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 Nicorette Dosing Log

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Date of Visit: [EXDATB]	
Session Start Time: [EXSRTTIM]	
Session End Time: [EXENDTIM]	

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

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

FORM STATUS CHANGE LOG

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

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

LOCKING HISTORY

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

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

CLINICAL DATA

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

CONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to take 10 puffs, with a max of 3 seconds per puff (+/-2 sec), at 30 second intervals (+/-5sec))	
Date of Visit: [EXDATVLN]	31-May-2018
Session Start Time: [EXSTTIM]	11:00
Row 1	
Puff: [EXPFF]	Puff 1
Puff Begin: [EXPFBG]	11:00:01
Puff End: [EXPFEN]	11:00:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 2	
Puff: [EXPFF]	Puff 2

Puff Begin: [EXPFBG]	11:00:33
Puff End: [EXPFEN]	11:00:36
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 3	
Puff: [EXPFF]	Puff 3
Puff Begin: [EXPFBG]	11:01:01
Puff End: [EXPFEN]	11:01:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 4	
Puff: [EXPFF]	Puff 4
Puff Begin: [EXPFBG]	11:01:30
Puff End: [EXPFEN]	11:01:32
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 5	
Puff: [EXPFF]	Puff 5
Puff Begin: [EXPFBG]	11:02:00

Puff End: [EXPFEN]	11:02:03
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 6	
Puff: [EXPFF]	Puff 6
Puff Begin: [EXPFBG]	11:02:30
Puff End: [EXPFEN]	11:02:33
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 7	
Puff: [EXPFF]	Puff 7
Puff Begin: [EXPFBG]	11:03:01
Puff End: [EXPFEN]	11:03:04
Missed Puff: [EXMISPF]	No
If yes, provide reason: [EXCOM]	
Row 8	
Puff: [EXPFF]	Puff 8
Puff Begin: [EXPFBG]	11:03:31
Puff End: [EXPFEN]	11:03:34

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]	PUFF NOT TAKEN DUE TO CIGARETTE BEING DONE
Row 10	
Puff: [EXPFF]	
Puff Begin: [EXPFBG]	
Puff End: [EXPFEN]	
Missed Puff: [EXMISPF]	Yes
If yes, provide reason: [EXCOM]	PUFF NOT TAKEN DUE TO CIGARETTE BEING DONE
Did the subject consume any beverages during controlled product use? [EXBEVB2]	No

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com ((b) (6)
Date/Time	07-Jun-2018 01:23 PM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EXDATVLN [EXDATVLN]		31-May-2018
EXSTTIM [EXSTTIM]		11:00
[Row 1] EXPFF [EXPFF]		Puff 1
[Row 1] EXPFBG [EXPFBG]		11:00:01
[Row 1] EXPFEN [EXPFEN]		11:00:04
[Row 1] EXMISPF [EXMISPF]		No
[Row 2] EXPFF [EXPFF]		Puff 2
[Row 2] EXPFBG [EXPFBG]		11:00:33
[Row 2] EXPFEN [EXPFEN]		11:00:36
[Row 2] EXMISPF [EXMISPF]		No
[Row 3] EXPFF [EXPFF]		Puff 3
[Row 3] EXPFBG [EXPFBG]		11:01:01
[Row 3] EXPFEN [EXPFEN]		11:01:04
[Row 3] EXMISPF [EXMISPF]		No
[Row 4] EXPFF [EXPFF]		Puff 4
[Row 4] EXPFBG [EXPFBG]		11:01:30
[Row 4] EXPFEN [EXPFEN]		11:01:32
[Row 4] EXMISPF [EXMISPF]		No
[Row 5] EXPFF [EXPFF]		Puff 5
[Row 5] EXPFBG [EXPFBG]		11:02:00

Variable	Old Value	New Value
[Row 5] EXPFEN [EXPFEN]		11:02:03
[Row 5] EXMISPF [EXMISPF]		No
[Row 6] EXPFF [EXPFF]		Puff 6
[Row 6] EXPFBG [EXPFBG]		11:02:30
[Row 6] EXPFEN [EXPFEN]		11:02:33
[Row 6] EXMISPF [EXMISPF]		No
[Row 7] EXPFF [EXPFF]		Puff 7
[Row 7] EXPFBG [EXPFBG]		11:03:01
[Row 7] EXPFEN [EXPFEN]		11:03:04
[Row 7] EXMISPF [EXMISPF]		No
[Row 8] EXPFF [EXPFF]		Puff 8
[Row 8] EXPFBG [EXPFBG]		11:03:31
[Row 8] EXPFEN [EXPFEN]		11:03:34
[Row 8] EXMISPF [EXMISPF]		No
[Row 9] EXMISPF [EXMISPF]		Yes
[Row 9] EXCOM [EXCOM]		PUFF NOT TAKEN DUE TO CIGARETTE BEING DONE
[Row 10] EXMISPF [EXMISPF]		Yes
[Row 10] EXCOM [EXCOM]		PUFF NOT TAKEN DUE TO CIGARETTE BEING DONE
EXBEVB2 [EXBEVB2]		No

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 01:23 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:04 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 11:57 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

UNCONTROLLED VERY LOW NICOTINE (VLN) (NON-MENTHOL) PRODUCT USE LOG (Subject to use ONE unit of product ad libitum for 10 minute; staff to document the duration of each puff)	
Date of Visit: [EXDATB]	31-May-2018
Session Start Time: [EXSRTTIM]	17:00
Session End Time: [EXENDTIM]	17:03
Row 1	
Inhalation Begin: [EXINHBG]	17:00:05
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:08
Time Unknown: [EXTIMUNK]	
Row 2	
Inhalation Begin: [EXINHBG]	17:00:13
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:15
Time Unknown: [EXTIMUNK]	
Row 3	
Inhalation Begin: [EXINHBG]	17:00:24

Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:27
Time Unknown: [EXTIMUNK]	
Row 4	
Inhalation Begin: [EXINHBG]	17:00:38
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:00:40
Time Unknown: [EXTIMUNK]	
Row 5	
Inhalation Begin: [EXINHBG]	17:01:09
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:01:11
Time Unknown: [EXTIMUNK]	
Row 6	
Inhalation Begin: [EXINHBG]	17:01:31
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:01:33
Time Unknown: [EXTIMUNK]	

Row 7	
Inhalation Begin: [EXINHBG]	17:02:05
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:02:06
Time Unknown: [EXTIMUNK]	
Row 8	
Inhalation Begin: [EXINHBG]	17:02:27
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:02:28
Time Unknown: [EXTIMUNK]	
Row 9	
Inhalation Begin: [EXINHBG]	17:03:47
Time Unknown: [EXTIMUNK]	
Inhalation End: [EXINEN]	17:03:48
Time Unknown: [EXTIMUNK]	

Did the subject consume any beverages during uncontrolled product use? [EXBEVB]	No
Session Total Inhalations: [EXINTOT]	9

AUDIT TRAIL

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

Logged in User	[redacted] vinceandassociates.com ([redacted]	
Date/Time	07-Jun-2018 01:36 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EX9DATB [EXDATB]		31-May-2018
EX9SRTTIM [EXSRTTIM]		17:00
EX9ENDTIM [EXENDTIM]		17:03
[Row 1] EX9INHBG [EXINHBG]		17:00:05
[Row 1] EX9INEN [EXINEN]		17:00:08
[Row 2] EX9INHBG [EXINHBG]		17:00:13
[Row 2] EX9INEN [EXINEN]		17:00:15
[Row 3] EX9INHBG [EXINHBG]		17:00:24
[Row 3] EX9INEN [EXINEN]		17:00:27
[Row 4] EX9INHBG [EXINHBG]		17:00:38
[Row 4] EX9INEN [EXINEN]		17:00:40
[Row 5] EX9INHBG [EXINHBG]		17:01:09
[Row 5] EX9INEN [EXINEN]		17:01:11
[Row 6] EX9INHBG [EXINHBG]		17:01:31
[Row 6] EX9INEN [EXINEN]		17:01:33
[Row 7] EX9INHBG [EXINHBG]		17:02:05
[Row 7] EX9INEN		17:02:06

Variable	Old Value	New Value
[EXINEN]		
[Row 8] EX9INHBG [EXINHBG]		17:02:27
[Row 8] EX9INEN [EXINEN]		17:02:28
[Row 9] EX9INHBG [EXINHBG]		17:03:47
[Row 9] EX9INEN [EXINEN]		17:03:48
EX9BEVB [EXBEVB]		No
EX9INTOT [EXINTOT]		9

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	07-Jun-2018 01:36 PM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:04 PM PDT (UTC-07:00)	Form marked as Not Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Expected
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

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

User	Date/Time	Status
(b) (6) gmail.com ((b) (6) (b) (6)	02-Aug-2018 11:57 AM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: ECG Test Results

Was the ECG performed? [EGYN]	Yes
Date: [EGDAT]	31-May-2018
Visit: [EGVIS]	Day 6
Row 1	
Time: [EGTIM]	20:08
Time Unknown: [EGTMNK]	
Position: [EGPOS]	SUPINE
VR: [EGVR]	54
PR Interval: [EGPR]	219
QRS Interval: [EGQRS]	100

QT Interval: [EGQT]	387
QTcB Interval: [EGQTCB]	367
QTcF: [EGQTCF]	374
Clinical Significance as per MD: [EGCLSIG]	ABNORMAL NCS
If Abnormal and Clinically Significant, please specify abnormalities: [EGCOM]	

AUDIT TRAIL

VISIT: Day 6
FORM: ECG Test Results

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:28 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
EG1YN [EGYN]		Yes
EG1DAT [EGDAT]		31-May-2018
EGVIS [EGVIS]		Day 6
[Row 1] EG1TIM [EGTIM]		20:08
[Row 1] EG1POS [EGPOS]		SUPINE
[Row 1] EGVR [EGVR]		54
[Row 1] EG1PR [EGPR]		219
[Row 1] EG1QRS [EGQRS]		100
[Row 1] EG1QT [EGQT]		387

Variable	Old Value	New Value
[Row 1] EGQTCB [EGQTCB]		367
[Row 1] EG1QTCF [EGQTCF]		374
[Row 1] EG1CLSIG [EGCLSIG]		ABNORMAL NCS

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: ECG Test Results

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	28-Jun-2018 08:59 AM PDT (UTC-07:00)	Form marked as Complete
System	06-Jun-2018 07:28 AM PDT (UTC-07:00)	Form marked as Not Complete
System	06-Jun-2018 07:28 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: ECG Test Results

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: Day 6
FORM: ECG Test Results

ID	Variable	Responses/Reasons	Opened	Closed
	[Row 1] EG1CLSIG	ABNORMAL NCS PER PRINCIPAL INVESTIGATOR [14-Jun-2018 09:31 AM by (b) (6) vinceandassociates.com ((b) (6) Response satisfies query [28-Jun-2018 08:59 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6)	06-Jun-2018 07:28 AM	28-Jun-2018 08:59 AM
	Description			
	New: Clinically Significant as per MD is Abnormal NCS. However, results are all within range. Please clarify. **Old:** **By:** 06-Jun-2018 07:28 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6)			

LOCKING HISTORY

VISIT: Day 6
FORM: ECG Test Results

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

CLINICAL DATA

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

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

Use: [QSUSE]	1st Use

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:29 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF [QSPERF]		Yes
QSUSE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:29 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

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

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:29 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF1 [QSPERF]		Yes
QSUSE_1 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:29 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:59 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) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:29 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF_1 [QSPERF]		Yes
QSUSE_2 [QSUSE]		1st Use

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:29 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

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

Use: [QSUSE]	2nd Use
Row 1	
Time point: [QSTMPT]	
Completed: [QSYN]	

AUDIT TRAIL

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

Logged in User	[redacted] vinceandassociates.com ([redacted]) [redacted]	
Date/Time	06-Jun-2018 07:29 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QSPERF2 [QSPERF]		Yes
QSUSE2 [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:29 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: End of Study

Visit Date [DSVDAT]	31-May-2018
Date of Completion or Discontinuation: [DSDAT]	31-May-2018
Date of Last Dose of Study Medication: [DSDOSDAT]	31-May-2018
Did the subject complete the study? [DSCOMYN]	Yes
If No, please mark the PRIMARY reason for discontinuation:	

Primary reason for study discontinuation: [DSDECOD]	
If Other, please specify: [DSTERM]	
Additional Comments: [DSCOM]	

AUDIT TRAIL

VISIT: Day 6
FORM: End of Study

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:30 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
DSVDAT1 [DSVDAT]		31-May-2018
DSDAT [DSDAT]		31-May-2018
DSDOSDT [DSDOSDAT]		31-May-2018
DSCOMYN [DSCOMYN]		Yes

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: End of Study

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:30 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: Day 6
FORM: End of Study

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
FORM: End of Study

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

CLINICAL DATA

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

Use: [PKUSE]	1st Use (Morning Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	10:55

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute

Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:11
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	A - Late due to difficult collection
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:20
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:30

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	11:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	12:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute

Date: [PKDAT]	31-May-2018
Time: [PKTIM]	12:31
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	B - Late due to previous procedure
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	13:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	13:35
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	A - Late due to difficult collection
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	14:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:34 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE1 [PKUSE]		1st Use (Morning Draw)
[Row 1] PKTPT [PKTPT]		Predose
[Row 1] PKDAT [PKDAT]		31-May-2018
[Row 1] PKTIM [PKTIM]		10:55
[Row 2] PKTPT [PKTPT]		2 minute
[Row 2] PKDAT [PKDAT]		31-May-2018

Variable	Old Value	New Value
[Row 2] PKTIM [PKTIM]		11:02
[Row 3] PKTPT [PKTPT]		5 minute
[Row 3] PKDAT [PKDAT]		31-May-2018
[Row 3] PKTIM [PKTIM]		11:05
[Row 4] PKTPT [PKTPT]		7 minute
[Row 4] PKDAT [PKDAT]		31-May-2018
[Row 4] PKTIM [PKTIM]		11:07
[Row 5] PKTPT [PKTPT]		10 minute
[Row 5] PKDAT [PKDAT]		31-May-2018
[Row 5] PKTIM [PKTIM]		11:11
[Row 5] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 6] PKTPT [PKTPT]		12 minute
[Row 6] PKDAT [PKDAT]		31-May-2018
[Row 6] PKTIM [PKTIM]		11:12
[Row 7] PKTPT [PKTPT]		15 minute
[Row 7] PKDAT [PKDAT]		31-May-2018
[Row 7] PKTIM [PKTIM]		11:15
[Row 8] PKTPT [PKTPT]		20 minute
[Row 8] PKDAT [PKDAT]		31-May-2018
[Row 8] PKTIM [PKTIM]		11:20
[Row 9] PKTPT [PKTPT]		30 minute

Variable	Old Value	New Value
[Row 9] PKDAT [PKDAT]		31-May-2018
[Row 9] PKTIM [PKTIM]		11:30
[Row 10] PKTPT [PKTPT]		45 minute
[Row 10] PKDAT [PKDAT]		31-May-2018
[Row 10] PKTIM [PKTIM]		11:45
[Row 11] PKTPT [PKTPT]		60 minute
[Row 11] PKDAT [PKDAT]		31-May-2018
[Row 11] PKTIM [PKTIM]		12:00
[Row 12] PKTPT [PKTPT]		90 minute
[Row 12] PKDAT [PKDAT]		31-May-2018
[Row 12] PKTIM [PKTIM]		12:31
[Row 12] PKCODE [PKCODE]		B - Late due to previous procedure
[Row 13] PKTPT [PKTPT]		120 minute
[Row 13] PKDAT [PKDAT]		31-May-2018
[Row 13] PKTIM [PKTIM]		13:00
[Row 14] PKTPT [PKTPT]		150 minute
[Row 14] PKDAT [PKDAT]		31-May-2018
[Row 14] PKTIM [PKTIM]		13:35
[Row 14] PKCODE [PKCODE]		A - Late due to difficult collection
[Row 15] PKTPT [PKTPT]		180 minute
[Row 15] PKDAT [PKDAT]		31-May-2018

Variable	Old Value	New Value
[Row 15] PKTIM [PKTIM]		14:00

FORM STATUS CHANGE LOG

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

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:34 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

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

Use: [PKUSE]	2nd Use (Afternoon Draw)
Row 1	
Timepoint: [PKTPT]	Predose
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	16:55
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 2	
Timepoint: [PKTPT]	2 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:02
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 3	
Timepoint: [PKTPT]	5 minute

Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:05
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 4	
Timepoint: [PKTPT]	7 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:07
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 5	
Timepoint: [PKTPT]	10 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:10
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 6	
Timepoint: [PKTPT]	12 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:12
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 7	
Timepoint: [PKTPT]	15 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:15
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 8	
Timepoint: [PKTPT]	20 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:20

Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 9	
Timepoint: [PKTPT]	30 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 10	
Timepoint: [PKTPT]	45 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	17:45
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 11	
Timepoint: [PKTPT]	60 minute

Date: [PKDAT]	31-May-2018
Time: [PKTIM]	18:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 12	
Timepoint: [PKTPT]	90 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	18:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 13	
Timepoint: [PKTPT]	120 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	19:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	

Comments: [PKCODE]	
Row 14	
Timepoint: [PKTPT]	150 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	19:30
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	
Row 15	
Timepoint: [PKTPT]	180 minute
Date: [PKDAT]	31-May-2018
Time: [PKTIM]	20:00
Not Done: [PKSTAT]	
Time Unknown [PKACTNK]	
Comments: [PKCODE]	

AUDIT TRAIL

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

Logged in User	(b) (6) [redacted] vinceandassociates.com (b) (6) (b) (6) (b) (6)
Date/Time	06-Jun-2018 07:40 AM PDT (UTC-07:00)

Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
PKUSE [PKUSE]		2nd Use (Afternoon Draw)
[Row 1] PKTPT1 [PKTPT]		Predose
[Row 1] PKDAT1 [PKDAT]		31-May-2018
[Row 1] PKTIM1 [PKTIM]		16:55
[Row 2] PKTPT1 [PKTPT]		2 minute
[Row 2] PKDAT1 [PKDAT]		31-May-2018
[Row 2] PKTIM1 [PKTIM]		17:02
[Row 3] PKTPT1 [PKTPT]		5 minute
[Row 3] PKDAT1 [PKDAT]		31-May-2018
[Row 3] PKTIM1 [PKTIM]		17:05
[Row 4] PKTPT1 [PKTPT]		7 minute
[Row 4] PKDAT1 [PKDAT]		31-May-2018
[Row 4] PKTIM1 [PKTIM]		17:07
[Row 5] PKTPT1 [PKTPT]		10 minute
[Row 5] PKDAT1 [PKDAT]		31-May-2018
[Row 5] PKTIM1 [PKTIM]		17:10
[Row 6] PKTPT1 [PKTPT]		12 minute
[Row 6] PKDAT1 [PKDAT]		31-May-2018
[Row 6] PKTIM1 [PKTIM]		17:12
[Row 7] PKTPT1 [PKTPT]		15 minute

Variable	Old Value	New Value
[Row 7] PKDAT1 [PKDAT]		31-May-2018
[Row 7] PKTIM1 [PKTIM]		17:15
[Row 8] PKTPT1 [PKTPT]		20 minute
[Row 8] PKDAT1 [PKDAT]		31-May-2018
[Row 8] PKTIM1 [PKTIM]		17:20
[Row 9] PKTPT1 [PKTPT]		30 minute
[Row 9] PKDAT1 [PKDAT]		31-May-2018
[Row 9] PKTIM1 [PKTIM]		17:30
[Row 10] PKTPT1 [PKTPT]		45 minute
[Row 10] PKDAT1 [PKDAT]		31-May-2018
[Row 10] PKTIM1 [PKTIM]		17:45
[Row 11] PKTPT1 [PKTPT]		60 minute
[Row 11] PKDAT1 [PKDAT]		31-May-2018
[Row 11] PKTIM1 [PKTIM]		18:00
[Row 12] PKTPT1 [PKTPT]		90 minute
[Row 12] PKDAT1 [PKDAT]		31-May-2018
[Row 12] PKTIM1 [PKTIM]		18:30
[Row 13] PKTPT1 [PKTPT]		120 minute
[Row 13] PKDAT1 [PKDAT]		31-May-2018
[Row 13] PKTIM1 [PKTIM]		19:00
[Row 14] PKTPT1 [PKTPT]		150 minute

Variable	Old Value	New Value
[Row 14] PKDAT1 [PKDAT]		31-May-2018
[Row 14] PKTIM1 [PKTIM]		19:30
[Row 15] PKTPT1 [PKTPT]		180 minute
[Row 15] PKDAT1 [PKDAT]		31-May-2018
[Row 15] PKTIM1 [PKTIM]		20:00

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	06-Jun-2018 07:40 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	Date/Time	Status
(b) (6) algopharm.com (b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: Day 6
FORM: Use Product Again - VAS

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

AUDIT TRAIL

VISIT: Day 6
FORM: Use Product Again - VAS

Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	12-Jun-2018 10:11 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
Logged in User	(b) (6) vinceandassociates.com ((b) (6)	
Date/Time	07-Jun-2018 01:39 PM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]	Yes	

Variable	Old Value	New Value
QS5USE [QSUSE]	1st Use	
Logged in User	(b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:42 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		1st Use

FORM STATUS CHANGE LOG

VISIT: Day 6
FORM: Use Product Again - VAS

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jun-2018 10:11 AM PDT (UTC-07:00)	Form marked as Complete
System	07-Jun-2018 01:39 PM PDT (UTC-07:00)	Form marked as Not Complete
System	06-Jun-2018 07:42 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FIELD STATUSES

VISIT: Day 6
FORM: Use Product Again - VAS

Variable	Row Number	User	Date/Time	Field status
QS5PERF		(b) (6) vinceandassociates.com (b) (6)	07-Jun-2018 01:39 PM PDT (UTC-07:00)	The status was set to Cleared
QS5USE		(b) (6) vinceandassociates.com (b) (6)	07-Jun-2018 01:39 PM PDT (UTC-07:00)	The status was set to Cleared

FORM APPROVAL

VISIT: Day 6
FORM: Use Product Again - VAS

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

LOCKING HISTORY

VISIT: Day 6
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 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	[redacted] vinceandassociates.com ([redacted]	
Date/Time	12-Jun-2018 10:11 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
QS5PERF [QSPERF]		Yes
QS5USE [QSUSE]		2nd Use

FORM STATUS CHANGE LOG

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

User	**Date/Time**	**Change**
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	12-Jun-2018 10:11 AM PDT (UTC-07:00)	Form marked as Complete
System	05-Jun-2018 01:42 PM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

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

User	**Date/Time**	**Status**
[redacted] algopharm.com ([redacted]	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
[redacted] gmail.com ([redacted]	07-Aug-2018 12:59 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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: Vital Signs

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

CLINICAL DATA

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

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

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

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: Chemistry Laboratory Evaluation

User	Date/Time	Change
(b) (6) vinceandassociates.com (b) (6)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

VISIT: Early Term
FORM: ECG Test Results

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

CLINICAL DATA

VISIT: Early Term
FORM: End of Study

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

Additional Comments: [DSCOM]	

FORM STATUS CHANGE LOG

VISIT: Early Term
FORM: End of Study

User	Date/Time	Change
(b) (6) vinceandassociates.com ((b) (6)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 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) algopharm.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)	07-Jun-2018 01:37 PM PDT (UTC-07:00)	Form marked as Not Expected
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

LOCKING HISTORY

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

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

CLINICAL DATA

VISIT: All Visits
FORM: Adverse Events

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

Severity: [AESEV]	MODERATE
Frequency: [AEFREQ]	Continuous
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	Yes
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Possibly Related
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	26-May-2018
Onset Time: [AESTTIM]	14:45
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	26-May-2018
End Time: [AEENTIM]	18:00
Time Unknown: [AEENTMNK]	
Row 2	
AE Identifier: [AESPID]	2

Adverse Event Term: [AETERM]	LOW BACK PAIN
Is this an SAE? [AESER]	No
Severity: [AESEV]	MODERATE
Frequency: [AEFREQ]	Continuous
Action Taken with Study Treatment: [AEACN]	No Action Taken
Was a concomitant treatment given because of the occurrence of the event? (If yes, record on Concomitant Medication Form) [AECONTRT]	Yes
Did the AE result in withdrawal from study? [AEDIS]	No
Relationship to Investigational Product: [AEREL]	Unrelated
Was this AE a result of Study Medication error? [AETEAE]	No
Outcome: [AEOUT]	Resolved
Onset Date: [AESTDAT]	29-May-2018
Onset Time: [AESTTIM]	21:30
Time Unknown: [AESTTMNK]	
AE Ongoing? [AEONGO]	No
End Date: [AEENDAT]	31-May-2018
End Time: [AEENTIM]	07:00
Time Unknown: [AEENTMNK]	

AUDIT TRAIL

VISIT: All Visits
FORM: Adverse Events

Logged in User	(b) (6) [redacted] vinceandassociates.com (b) (6) (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:54 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
[Row 1] AEDIS [AEDIS]		No
[Row 2] AECMNM_deleted [AECMNM_deleted]		2
[Row 2] AESPID [AESPID]		2
[Row 2] AETERM [AETERM]		LOW BACK PAIN
[Row 2] AESER [AESER]		No
[Row 2] AESEV [AESEV]		MODERATE
[Row 2] AEFREQ [AEFREQ]		Continuous
[Row 2] AEACN [AEACN]		No Action Taken
[Row 2] AECONTRT [AECONTRT]		Yes
[Row 2] AEDIS [AEDIS]		No
[Row 2] AEREL [AEREL]		Unrelated
[Row 2] AETEAE [AETEAE]		No
[Row 2] AEOUT [AEOUT]		Resolved
[Row 2] AESTDAT [AESTDAT]		29-May-2018
[Row 2] AESTTIM [AESTTIM]		21:30
[Row 2] AEONGO		No

Variable	Old Value	New Value
[AEONGO]		
[Row 2] AEENDAT [AEENDAT]		31-May-2018
[Row 2] AEENTIM [AEENTIM]		07:00
Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:53 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
AEYN [AEYN]		Yes
Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:53 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
[Row 1] AECMNM_deleted [AECMNM_deleted]		1
[Row 1] AESPID [AESPID]		1
[Row 1] AETERM [AETERM]		HEADACHE
[Row 1] AESER [AESER]		No
[Row 1] AESEV [AESEV]		MODERATE
[Row 1] AEFREQ [AEFREQ]		Continuous
[Row 1] AEACN [AEACN]		No Action Taken
[Row 1] AECONTRT [AECONTRT]		Yes
[Row 1] AEREL [AEREL]		Possibly Related
[Row 1] AETEAE [AETEAE]		No
[Row 1] AEOUT		Resolved

Variable	Old Value	New Value
[AEOUT]		
[Row 1] AESTDAT [AESTDAT]		26-May-2018
[Row 1] AESTTIM [AESTTIM]		14:45
[Row 1] AEONGO [AEONGO]		No
[Row 1] AEENDAT [AEENDAT]		26-May-2018
[Row 1] AEENTIM [AEENTIM]		18:00

FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Adverse Events

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:54 AM PDT (UTC-07:00)	Form marked as Complete
System	06-Jun-2018 07:53 AM PDT (UTC-07:00)	Form marked as Not Complete
System	06-Jun-2018 07:53 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 AM PDT (UTC-07:00)	Form marked as Not Complete

FORM APPROVAL

VISIT: All Visits
FORM: Adverse Events

User	Date/Time	Status
(b) (6) algopharm.com ((b) (6) (b) (6)	04-Oct-2018 05:56 AM PDT (UTC-07:00)	Form marked as "Freeze".
dkelsh (Debra Kelsh)	04-Oct-2018 05:33 AM PDT (UTC-07:00)	Form marked as "Form Signed". (All data included in this electronic Case Report form (eCRF) has been carefully recorded and reviewed. I confirm that to the best of my knowledge it accurately reflects the study information obtained for this subject) - ESignature
(b) (6) gmail.com ((b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: All Visits
FORM: Adverse Events

ID	Variable	Responses/Reasons	Opened	Closed
	AEYN	Data Updated [06-Jun-2018 07:53 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	06-Jun-2018 07:53 AM	06-Jun-2018 07:53 AM
	Description			
	New: Answer is missing, please review **Old:** **By:** 06-Jun-2018 07:53 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) (b) (6)			
	[Row 1] AEDIS	Data Updated [06-Jun-2018 07:54 AM by (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6)	06-Jun-2018 07:53 AM	06-Jun-2018 07:54 AM
	Description			
	New: Answer is missing, please review **Old:** **By:** 06-Jun-2018 07:53 AM (b) (6) vinceandassociates.com ((b) (6) (b) (6) (b) (6) (b) (6)			

LOCKING HISTORY

VISIT: All Visits
FORM: Adverse Events

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

CLINICAL DATA

VISIT: All Visits
FORM: Concomitant Medications

Were there any medications the subject has taken in the past 30 days and throughout the study? [CMYN]	Yes

Row 1	
CM Number: [CMNUM]	1
Medication/Therapy/Procedure: [CMTRT]	ACETAMINOPHEN
Indication: [CMINDC]	Adverse Event
If Other, please specify: [CMINDOT]	
Adverse Event #: [CMAENUM]	1
Medical History #: [CMMHNUM]	
Strength: [CMDOSE]	325
Unit: [CMDOSU]	mg
If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	2
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	650

Unit: [CMTOTUN]	mg
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	ONCE
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	26-May-2018
Start Time: [CMSTTIM]	16:48
Time Unknown [CMSTTNK]	
End Date: [CMENDAT]	26-May-2018
End Time: [CMENTIM]	16:48
Time Unknown [CMENTNK]	
Ongoing? [CMONGO]	
Row 2	
CM Number: [CMNUM]	2
Medication/Therapy/Procedure: [CMTRT]	ACETAMINOPHEN
Indication: [CMINDC]	Adverse Event
If Other, please specify: [CMINDOT]	

Adverse Event #: [CMAENUM]	2
Medical History #: [CMMHNUM]	
Strength: [CMDOSE]	325
Unit: [CMDOSU]	mg
If Other, please specify: [CMDOSOTH]	
Quantity: [CMQUANT]	2
Form: [CMDOSFRM]	TABLET
If Other, please specify: [CMFRMOT]	
Total Dose: [CMTOTDOS]	650
Unit: [CMTOTUN]	mg
If Other, please specify: [CMUNOT]	
Route: [CMROUTE]	ORAL
If other, please specify: [CMOTHER]	
Frequency: [CMDOSFRQ]	ONCE
If Other, please specify: [CMFRQOT]	
Start Date: [CMSTDAT]	29-May-2018
Start Time: [CMSTTIM]	22:38
Time Unknown [CMSTTNK]	

End Date: [CMENDAT]	29-May-2018
End Time: [CMENTIM]	22:38
Time Unknown [CMENTNK]	
Ongoing? [CMONGO]	

AUDIT TRAIL

VISIT: All Visits
FORM: Concomitant Medications

Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:50 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Reason for change:	Data entry error	
Variable	**Old Value**	**New Value**
CMYN [CMYN]		Yes
Logged in User	(b) (6) (b) (6) vinceandassociates.com (b) (6) (b) (6)	
Date/Time	06-Jun-2018 07:50 AM PDT (UTC-07:00)	
Application Used	Web Browser (EDC)	
Subject Entry	No	
Variable	**Old Value**	**New Value**
[Row 1] CMNUM [CMNUM]		1
[Row 1] CMTRT [CMTRT]		ACETAMINOPHEN
[Row 1] CMINDC [CMINDC]		Adverse Event
[Row 1] CMAENUM [CMAENUM]		1
[Row 1] CMDOSE [CMDOSE]		325
[Row 1] CMDOSU [CMDOSU]		mg

Variable	Old Value	New Value
[Row 1] CMQUANT [CMQUANT]		2
[Row 1] CMDOSFRM [CMDOSFRM]		TABLET
[Row 1] CMTOTDOS [CMTOTDOS]		650
[Row 1] CMTOTUN [CMTOTUN]		mg
[Row 1] CMROUTE [CMROUTE]		ORAL
[Row 1] CMDOSFRQ [CMDOSFRQ]		ONCE
[Row 1] CMSTDAT [CMSTDAT]		26-May-2018
[Row 1] CMSTTIM [CMSTTIM]		16:48
[Row 1] CMENDAT [CMENDAT]		26-May-2018
[Row 1] CMENTIM [CMENTIM]		16:48
[Row 2] CMNUM [CMNUM]		2
[Row 2] CMTRT [CMTRT]		ACETAMINOPHEN
[Row 2] CMINDC [CMINDC]		Adverse Event
[Row 2] CMAENUM [CMAENUM]		2
[Row 2] CMDOSE [CMDOSE]		325
[Row 2] CMDOSU [CMDOSU]		mg
[Row 2] CMQUANT [CMQUANT]		2
[Row 2] CMDOSFRM [CMDOSFRM]		TABLET
[Row 2] CMTOTDOS [CMTOTDOS]		650
[Row 2] CMTOTUN [CMTOTUN]		mg
[Row 2] CMROUTE [CMROUTE]		ORAL

Variable	Old Value	New Value
[Row 2] CMDOSFRQ [CMDOSFRQ]		ONCE
[Row 2] CMSTDAT [CMSTDAT]		29-May-2018
[Row 2] CMSTTIM [CMSTTIM]		22:38
[Row 2] CMENDAT [CMENDAT]		29-May-2018
[Row 2] CMENTIM [CMENTIM]		22:38

FORM STATUS CHANGE LOG

VISIT: All Visits
FORM: Concomitant Medications

User	Date/Time	Change
System	26-Oct-2018 01:27 PM PDT (UTC-07:00)	Form marked as Complete Final
System	06-Jun-2018 07:50 AM PDT (UTC-07:00)	Form marked as Complete
System	06-Jun-2018 07:50 AM PDT (UTC-07:00)	Form marked as Not Complete
System	06-Jun-2018 07:50 AM PDT (UTC-07:00)	Form marked as Complete
System	31-May-2018 09:34 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

User	Date/Time	Status
(b) (6) gmail.com (b) (6) (b) (6)	07-Aug-2018 12:59 PM PDT (UTC-07:00)	Form marked as "Form Monitored".

QUERIES

VISIT: All Visits
FORM: Concomitant Medications

ID	Variable	Responses/Reasons	Opened	Closed
	CMYN	Data Updated [06-Jun-2018 07:50 AM by (b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)	06-Jun-2018 07:50 AM	06-Jun-2018 07:50 AM
	Description			
	New: Answer is missing, please review **Old:** **By:** 06-Jun-2018 07:50 AM (b) (6) vinceandassociates.com (b) (6) (b) (6) (b) (6)			

LOCKING HISTORY

VISIT: All Visits
FORM: Concomitant Medications

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