

CRF Report for Study E6270229

Patient: 4003
CRF: Header_Page
Visit: SCREENING
Entered By: Tricia Hunt
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CP_001
Blank? N
Visit Date: 02-02-2007
Entry Time: 02-04-2007 14:26:29
Modification Time: 17-10-2007 11:46:46
Approval Time:
Verification Time:

Investigator: CP_001
CRF Page #: 1
Document #: R136657413
CRF Status: Entry Complete
Approver:
Verifier:

Section: Header_Info	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Section Date: 02-02-2007	
Entered By: Tricia Hunt	Entry Time: 02-04-2007 14:26:29	
	Last Modification Time: 02-04-2007 14:26:51	
	Page number: 1	
<div>RDC CASE REPORT FORMSMOKER</div> <div>Sponsor NameInvestigatorSite</div> <div>RJ REYNOLDS TOBACCO COMPANYKEITH KLATT, MD4</div> <div>SWITCHING FROM USUAL BRAND CIGARETTES TO A TOBACCO-HEATING CIGARETTE OR SNUS</div> <div>-A MULTI-CENTER EVALUATION OF HEALTH-RELATED QUALITY OF LIFE ASSESSMENTS AND BIOMARKERS</div> <div>OF EXPOSURE AND HARM</div>		

[Click here to navigate to response history for this CRF](#)

Page ID: D11551613

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Portland

Investigator: Keith Klatt

Date: 25-APR-2008

Patient#: 4003

Patient Initials:

Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
HDYF?/Oral Health Questions Inquiry WEEK 12 Disc ID: 1319967413 Type: MANUAL HEADER	15 11MAY07 Closed: N	W12 HDYF? Inquiry data is not provided.	Date= 17FE MAR 25APR2008 Actual Time= 1230 HDYF Performed?= yes Comments= not done - pt. ET'D
Laboratory Evaluation SCREENING Disc ID: 1319960213 Type: MANUAL HEADER	2 02FEB07 Closed: N	Screening lab req #N574619 shows a gender of 'F', however this subject is Male. Please provide an updated lab req.	<input checked="" type="checkbox"/> Updated req attached <input type="checkbox"/> Other: _____

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Heather Kline
Authorized Personnel Signature

25 APR 2008
Date

Covance CLS

Marietta Henry, M.D., Director
 8211 SciCor Drive - Indianapolis, IN 46214-2985
 Tel. +1 (800) 327 7270

LABORATORY REPORT

**** REPRINTED: 25-APR-2008 ****

ACCESSION NO. N574619

Page 1 of 3

INVESTIGATOR: (J14315)

Keith Klatt, M.D.
 c/o Heather Aiona
 Covance - Portland
 5331 SW Macadam Ave
 Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
 Medical Director
 Covance CRU, Inc.
 3402 Kinsman Boulevard
 Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
 Significant/ Adverse
 Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.5		0.2-1.2 mg/dL		
Alk Phos	61		31-106 U/L		
ALT (SGPT)	45	H	6-34 U/L	[]	[✓]
AST (SGOT)	26		9-34 U/L		
GGT	42		4-49 U/L		
LDH	156		53-234 U/L		
Urea Nitr	21		4-24 mg/dL		
Creatinine	1.2	H	0.4-1.1 mg/dL	[]	[✓]
Glucose	103		70-115 mg/dL		
Uric Acid	7.4	H	2.1-7.2 mg/dL	[]	[✓]
Calcium	10.2		8.3-10.6 mg/dL		
Phosphorus	3.9		2.2-5.1 mg/dL		
Total Prot	7.0		6.1-8.4 g/dL		
Albumin	4.5		3.3-4.9 g/dL		
Sodium	143		132-147 mEq/L		
Potassium	4.4		3.4-5.4 mEq/L		
Chloride	105		94-112 mEq/L		

Investigator Signature:

Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
 T=Telephoned P="Panic" EX-Exclusion-as specified by the sponsor

J14315

(INV)

Covance CLS

Marietta Henry, M.D., Director
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HEMATOLOGY& DIFFERENTIAL PANEL

HGB	17.5	H	11.6-16.4 g/dL
HCT	50	H	34-48 %
RBC	5.4		4.1-5.6x10 ⁶ /uL
MCV	92		79-98 fL
MCH	32		26-34 pg
MCHC	35		31-38 g/dL
RDW	12.5		12.0-15.0 %
RBC Morph	Normocytic		
WBC	6.36		3.80-10.70 x10 ³ /uL
Neutrophil	4.00		1.96-7.23 x10 ³ /uL
Lymphocyte	1.86		0.91-4.28 x10 ³ /uL
Monocytes	0.28		0.12-0.92 x10 ³ /uL
Eosinophil	0.20		0.00-0.57 x10 ³ /uL
Basophils	0.03		0.00-0.20 x10 ³ /uL
Neutrophil	62.9		40.5-75.0 %
Lymphocyte	29.3		15.4-48.5 %
Monocytes	4.4		2.6-10.1 %
Eosinophil	3.1		0.0-6.8 %
Basophils	0.4		0.0-2.0 %
Platelets	166		140-400 x10 ³ /uL

Investigator Signature:

28 Apr 2008
Date:

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Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.009	1.003-1.035
pH	5.0	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Negative	


Investigator Signature:
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Yes

No

HEPATITIS B SURFACE ANTIGEN

HBSAG

Negative

No Ref Rng

HEPATITIS C VIRUS ANTIBODY

ANTI-HCV

Negative

No Ref Rng

HEPATITIS B SURFACE ANTIBODY

HBSAB

Negative

No Ref Rng

ESTRADIOL - See Note #1

Note #1 - No specimen received

Investigator Signature:

28 Apr 2008
Date:

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ACCESSION NO. NS74619

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Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive



Investigator Signature:

22 Apr 2008
Date:

"This testing is performed as part of a clinical trial. Diagnostic testing shall be conducted locally." H(High) or L(Low)-Values above or below Covance reference range T-Telephoned P-"Panic" EX-Exclusions as specified by the Sponsor

J14315

(INV)

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Significant/ Adverse
Event?

Yes

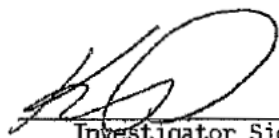
No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

IS SUBJECT A SMOKER OR NON-SM?

smoker/non Smoker



Investigator Signature:

28 Apr 2008
Date:

J14315

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SEX: M BIRTHDATE: (b) (6) AGE: 31

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Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 107 30-160 ug/dL

FOLLICLE STIMULATING HORMONE

FSH 6.0

Follicular:

4.0-13.0 mIU/mL

Mid-Cycle:

5.0-22.0 mIU/mL

Luteal:

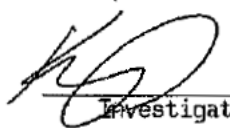
2.0-13.0 mIU/mL

Postmenopausal:

20.0-138.0 mIU/mL

HEPATITIS A ANTIBODY-IGM

HepA IgMab Negative No Ref Rng


Investigator Signature:

28 Apr 2008
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
T-Telephoned P-"Panic" EX-Exclusion-as specified by the sponsor

J14315

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

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SCREENING NUMBER: S4019

Is this Clinically
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Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng: Negative



Investigator Signature:

28 Apr 2008
Date:

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J14315

(INV)

Data Clarification Form

To: Covance CRU Portland

Investigator: Keith Klatt

Date: 25-APR-2008

Patient#: 4003

Patient Initials: .

Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
HDYF?/Oral Health Questions Inquiry WEEK 12 Disc ID: 1319967413 Type: MANUAL HEADER	15 11MAY07 Closed: N	W12 HDYF? Inquiry data is not provided.	Date= 17 APR 25 APR 2008 Actual Time= 0730 HDYF Performed? = yes Comments= not done - PC ET'D
Laboratory Evaluation SCREENING Disc ID: 1319960213 Type: MANUAL HEADER	2 02FEB07 Closed: N	Screening lab req #N574619 shows a gender of 'F', however this subject is Male. Please provide an updated lab req.	[] Updated req attached (2) [] Other: _____

① requested verification of lab for submission Rmd 042808
② noted as checked as req's are attached Rmd 042808

Tf
25 APR 08Rmd
25 APR 08
①

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Heather A. Kline
Authorized Personnel Signature

25 APR 2008
Date

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Lymphocyte	1.86		0.91-4.28 x10 ³ /uL		
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Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative-Trace
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Leuk Est	Negative	Ref Rng: Negative
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Keith Klatt, M.D.
c/o Heather Aiona
Covance - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229**INVESTIGATOR NO.: 4****RANDOMIZATION NUMBER: R4003****PATIENT INITIALS: (b) (6)****VISIT: 1****Screen****COLLECTION TIME: 10:34 DATE: 02-Feb-2007****DATE RECEIVED IN LABORATORY: 03-Feb-2007****DATE REPORTED BY LABORATORY: 03-Feb-2007****SEX: M BIRTHDATE: (b) (6) AGE: 31****SCREENING NUMBER: S4019**

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B SURFACE ANTIGEN

HBSAG Negative No Ref Rng

HEPATITIS C VIRUS ANTIBODY

ANTI-HCV Negative No Ref Rng

HEPATITIS B SURFACE ANTIBODY

HBSAB Negative No Ref Rng

ESTRADIOL - See Note #1

Note #1 - No specimen received

Investigator Signature:**Date:**

H(High) or L(Low)-Values above or below Covance CLS reference range
T-Telephoned P="Panic" EX-Exclusion-as specified by the sponsor

J14315

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

*** REPRINTED: 25-APR-2008 ***

ACCESSION NO: N574619

Page 1 of 1

INVESTIGATOR: (J14315)
Keith Klatt, M.D.
c/o Heather Aiona
Covance - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:
Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 4
RANDOMIZATION NUMBER: R4003
PATIENT INITIALS: (b) (6)
VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007
DATE RECEIVED IN LABORATORY: 03-Feb-2007
DATE REPORTED BY LABORATORY: 03-Feb-2007
SEX: M BIRTHDATE: (b) (6) AGE: 31
SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2 Non-Reactive Reference Range:
Non-Reactive

Investigator Signature:

Date:

"This testing is performed as part of a clinical trial. Diagnostic testing shall be conducted locally." H(High) or L(Low)=Values above or below Covance reference range T=Telephoned P="Panic" EX=Exclusions as specified by the Sponsor

J14315

(INV)

Covance CLS

Marietta Hensy, M.D., Director
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LABORATORY REPORT

*** REPRINTED: 25-APR-2008 ***

ACCESSION NO. N574619

Page 1 of 1

INVESTIGATOR: (J14315)

Keith Klatt, M.D.
c/o Heather Aiona
Covance - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: 54019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

IS SUBJECT A SMOKER OR NON-SM?

smoker/non Smoker

Investigator Signature:

Date:

J14315

(b)(6)

Covance CLS

Mariella Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2905
Tel. +1 (800) 327 7270

LABORATORY REPORT

*** REPRINTED: 25-APR-2008 ***

ACCESSION NO. N574619

Page 1 of 1

INVESTIGATOR: (J14315)
Keith Klatt, M.D.
c/o Heather Aiona
Covance - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:
Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 4
RANDOMIZATION NUMBER: R4003
PATIENT INITIALS: (b) (6)
VISIT: 1

Screen
COLLECTION TIME: 10:34 DATE: 02-Feb-2007
DATE RECEIVED IN LABORATORY: 03-Feb-2007
DATE REPORTED BY LABORATORY: 03-Feb-2007
SEX: M BIRTHDATE: (b) (6) AGE: 31
SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes No

TOTAL IRON
Total Iron 107 30-160 ug/dL

FOLLICLE STIMULATING HORMONE
FSH 6.0
Follicular:
4.0-13.0 mIU/mL
Mid-Cycle:
5.0-22.0 mIU/mL
Luteal:
2.0-13.0 mIU/mL
Postmenopausal:
20.0-138.0 mIU/mL

HEPATITIS A ANTIBODY-IGM
HepA IgM Ab Negative No Ref Rng

Investigator Signature:

Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX-Exclusion-as specified by the sponsor

J14315

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2905
Tel. +1 (800) 327 7270

LABORATORY REPORT

*** REPRINTED: 25-APR-2008 ***

ACCESSION NO. N574619

Page 1 of 1

INVESTIGATOR: (J14315)

Keith Klatt, M.D.
c/o Heather Aiona
Covance - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative

Ref Rng: Negative

Investigator Signature:

Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

J14315

(INV)

Page ID: D11769413

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Portland
Investigator: Keith Klatt
Date: 19-MAR-2008

Patient#: 4003
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
24-Hour Urine Collection WEEK 0 (BASELINE) Disc ID: 1357780713 Type: MANUAL HEADER	16FEB07 Closed: N	Disc ID 1319965713 requested a copy of lab req N528277. Document provided is the shipping requisition. Please forward the laboratory results document, req #N528277.	<input checked="" type="checkbox"/> Lab documents attached <input type="checkbox"/> Other: _____

Dm2
040808

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Authorized Personnel Signature

Date

07 APR 2008

Page 1 of 1

DCF ID: 51208313

Revision #: 0

Covance CLS

Marietta Henry, M.D., Director
8211 Scifor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N528277

Page 1 of 1

INVESTIGATOR: (J14315)

Keith Klatt, M.D.
c/o Heather Aiona
Radiant Research - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 17:18 DATE: 16-Feb-2007

DATE RECEIVED IN LABORATORY: 20-Feb-2007

DATE REPORTED BY LABORATORY: 20-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR - See Note #1

ELAPSED DATE AND TIME, 24HR

Elpsd D&T 1440 min

24 HR COLLECTION INFORMATION

Start Date 16-Feb-2007
Start Time 17:18
Stop Date 17-Feb-2007
Stop Time 17:18

TOTAL 24HR URINE VOLUME

Total Vol. 6500 mL

Note #1 - No specimen received

Investigator Signature:

26 Feb 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

J14315

(INV)

Data Clarification Form

To: Covance CRU Portland
Investigator: Keith Klatt
Date: 25-FEB-2008

Patient#: 4003
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
24-Hour Urine Collection WEEK 0 (BASELINE) Disc ID: 1319965713 Type: MANUAL	5 16FEB07 Closed: N	1-Please confirm that the following data, recorded for the W0 Spot Urine Void can be updated to 'NA'. 2-W0 Urine collection lab req (N528277) was not provided with this crf.	1- <input checked="" type="checkbox"/> Stop date=NA Stop time=NA [] Stop date=____ Stop time=____ 2- <input checked="" type="checkbox"/> Lab Req attached [] Other:
24-Hour Urine Collection WEEK 12 Disc ID: 1319967513 Type: MANUAL	15 11MAY07 Closed: N	1-Please confirm that the following data, recorded for the W12 Spot Urine Void can be updated to 'NA'. 2-Stop date/time and volume for the 24 hour urine collection are marked as 'NA'. Please clarify.	1- <input checked="" type="checkbox"/> Stop date=NA Stop time=NA [] Stop date=____ Stop time=____ 2-[] Window collection Not Done~ All fields=ND [] Stop date=____ Stop time=____:____ Volume=____ [X] Other: <i>pt. failed UA at beginning of visit</i>

① request for lab doc dm 2031908

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Heather Doria
Authorized Personnel Signature

27 FEB 28 2008
Date

COVANCE

THE DEVELOPMENT SERVICES COMPANY

Covance Central Laboratory Services, Inc.

8211 SciCor Dr.

Indianapolis, IN 46214-2985

800/327-7270

Fax: 317/616-2351

Accession No.

N528277

THE ACCESSION NUMBER IS
THE REFERENCE NUMBER
FOR COMMUNICATION WITH
COVANCE.**VISIT: 24 HR URINE COLLECTION**COMPLETE ALL BOXES IN THIS SECTION WITH BLACK BALL POINT
PEN. FAILURE TO COMPLETE ALL BOXES WILL DELAY REPORTS.

Screening Number

S**04****0****1****9**

(Subject)

Randomization Number

R**04****0****0****3**

(Subject)

Patient Initials

(If no middle initial, a dash will be
used)**(b) (6)****(b) (6)****(b) (6)****(b) (6)**

Birthdate

Complete month field in English
(Example: 02 JUN 1968)**(b) (6)****(b) (6)****(b) (6)****(b) (6)**

Sex

Male**Female**

Collection Date

Complete month field in English
(Example: 01 JAN 2001)**11****11****11****11****11**

Record the 24 Hr Urine start date.

Collection Time

(Record Midnight as 23:59)

17:18**17:18****17:18****17:18****17:18**

Record the 24 Hr Urine start time.

Requisition Completed by

Full name in capital letters

ANGELA REDD**ANGELA REDD****ANGELA REDD****ANGELA REDD****ANGELA REDD**

Samples Collected by

Full name in capital letters

ANGELA REDD**ANGELA REDD****ANGELA REDD****ANGELA REDD****ANGELA REDD****Note: Start Time for the 24-Hr Urine collection is the time the bladder
is emptied (after the Spot Urine Collection).**

24 Hour Urine Collection	Collection Date (DD/MMM/YYYY)	Collection Time (24 Hr clock)
Start	Same as Collection Date	Same as Collection Time
Stop	11 Feb 2007	17:18
Total Volume	10500	ml

REQUIRED TESTING – refer to pages 2 and 3 for collection and shipping instructions**AUTHORIZATION IS REQUIRED FOR ADDITIONAL TESTING**

Comments:

During in-house clinic visit

WHITE COPY – COVANCE

YELLOW COPY –

PINK COPY – INVESTIGATOR

SEND TO COVANCE LABORATORIES LTD.,
HARROGATE ENGLAND**PLEASE DO NOT RETURN EMPTY CONTAINERS TO COVANCE.****Covance internal use ONLY**

L6

509716



KMB 061226

3-part

**Covance
internal
use
ONLY**

Employee Visa

Tube Count

Ambient=

Frozen=

Refrig=

Slides=

Validation

First Entry

Second Entry

T-3

Data Clarification Form

To: Covance CRU Portland
Investigator: Keith Klatt
Date: 25-FEB-2008

Patient#: 4003
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Laboratory Evaluation WEEK 12 Disc ID: 1319968013 Type: MANUAL HEADER	11MAY07 Closed: N	No lab req's were provided for the W12 visit, nor were the Laboratory Evaluation fields populated. Please clarify.	<input checked="" type="checkbox"/> No lab evaluations were conducted for W12 <input type="checkbox"/> Lab req's attached Date: _____ Samples Obtained? Yes CS labs?: _____ <input type="checkbox"/> Other: _____
Laboratory Evaluation WEEK 0 (BASELINE) Disc ID: 1319966113 Type: MANUAL	5 16FEB07 Closed: N	Please verify the date to be associated with lab req #N528277.	<input checked="" type="checkbox"/> 16-02-2007 start <input type="checkbox"/> 17-02-2007

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Heather Aconia
Authorized Personnel Signature

27 FEB 2008
Date

Data Clarification Form

To: Covance CRU Portland
Investigator: Keith Klatt
Date: 25-FEB-2008

Patient#: 4003
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Usual Brand Cigarette Butt Collection WEEK 0 (BASELINE) Disc ID: 1319966213 Type: MANUAL	5.1 17FEB07 Closed: N	Response to the W0 'Usual Brand Cigarette Butt Collection' Any Product Deviation? Question is 'No', - however response is provided for 'If yes, number of butts other than usual brand' is provided.	<input checked="" type="checkbox"/> Delete 'N/A' - no deviations <input type="checkbox"/> Other: _____

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Deborah K. Smith
Authorized Personnel Signature

27 FEB 2008
Date

Page ID: D11448313

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Portland
Investigator: Keith Klatt
Date: 06-FEB-2008

Patient#: 4003
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Physical Exam WEEK 0 (BASELINE) Disc ID: 1304000913 Type: MANUAL	5 16FEB07 Closed: N	Relevant Findings for 'Other' is indicated as 'NO'. Please clarify response.	<input checked="" type="checkbox"/> Change response to 'Not Examined'. <input type="checkbox"/> Other (specify)

22
25 FEB 08

I have completed, reviewed and either approved all the corrections on this form or made some corrections and initialled those changes. I verify that I have received a copy of this form which will be filed with my copy of the appropriate Case Report Form.


Authorized Personnel Signature

12 FEB 2008
Date

CRI Report for Study E6270229

Patient: 4003
 CRF: Screening
 Visit: SCREENING
 Entered By: Tricia Hunt
 Discrepancies: Closed
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CP_001
 Blank? N
 Visit Date: 02-02-2007
 Entry Time: 15-05-2007 14:08:12
 Modification Time: 20-12-2007 10:26:58
 Approval Time:
 Verification Time:

Investigator: CP_001
 CRF Page #: 2
 Document #: R141898213
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:08:12	
		Last Modification Time: 25-05-2007 11:36:19	
		Page number: 2	

INCLUSION CRITERIA		
Sequence number		Yes/No
01	Males of females, between 31 and 55 years of age, inclusive.	YES
02	Subjects in Groups A, B, and C, must be cigarette-only smokers who currently smoke at least 15 cigarettes daily and who have smoked for at least 10 years prior to Week 0 (i.e., chronic cigarette smokers).	YES
03	Smokers of ultralight, regular, and menthol cigarettes will be eligible.	YES
04	Not intending to quit smoking, but willing to switch their tobacco product (intent to quit is defined as intending to make or making a quit attempt within 1 month prior to Week 0).	YES
05	Subjects for Group D must be self-reported never smokers per the ATS definition (see The American Thoracic Society Questionnaire).	NA, GROUP
06	Subjects must, in the opinion of the Investigators, be free of clinically significant health problems.	YES
07	Not be on medication on a daily basis for chronic medical disorders deemed clinically significant by the Investigator.	YES
08	Not be regularly taking creatine supplements.	YES
09	Negative test for selected drugs of abuse at Screening (includes alcohol test).	YES
10	Negative hepatitis panel (including HBsAg and anti-HCV) and negative HIV antibody screens (for subjects who have been immunized against hepatitis B and have documentation of this immunization, a positive result for HBsAg is not exclusionary).	YES

Section: Inc_Criteria	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:08:12	
		Last Modification Time: 25-05-2007 11:38:19	
		Page number: 20	

INCLUSION CRITERIA	
Sequence number	Yes/No
Females will be non-pregnant (for all females, the pregnancy test results must be negative	

CRF Report for Study E6270229

Patient: 4003

CRF: Screening

Visit: SCREENING

Site: CP_001

Blank? N

Visit Date: 02-02-2007

Investigator: CP_001

CRF Page #: 2

Document #: R141898213

Section:	Inc_Criteria	2 of 10	
11	at Screening; and for all females of child-bearing potential, the pregnancy test results must be negative at Weeks 0, 12, and 24), non-lactating, and either postmenopausal (as verified by FSH levels) for at least 1 year, surgically sterile (e.g. tubal ligation, hysterectomy, etc.) for at least 90 days, or agree to use from the time of signing the informed consent until 30 days after Week 24 (of Study Completion) a form of contraception considered acceptable to the Investigators (such as oral, injectable, or implantable contraceptives, intrauterine devices and barrier methods).		NOT AP
12	Able to comprehend and willing to sign an Informed Consent Form (ICF).		YES
13	Able to read and comprehend questionnaires in English.		YES

Section:	Exc_Criteria	3 of 10	Blank?	N	Section Status:	Entry Complete
Visit:	SCREENING		Section Date:	02-02-2007		
Entered By:	Tricia Hunt		Entry Time:	15-05-2007 14:08:12		
			Last Modification Time:	15-05-2007 14:12:04		
			Page number:	3		
Exclusion Criteria						
Sequence number						Yes/No
01	For Groups A, B, and C, regular use of any other tobacco or nicotine-containing product or device other than tobacco burning cigarettes from 6 months prior to the study through Week 24, including cigars, pipes, chewing tobacco, snuff, snus, nicotine patch, nicotine gum, etc.					NO
02	History or clinical manifestations of significant metabolic, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal, urological, neurological, or psychiatric disorders.					NO
03	History of hypersensitivity or allergies to any drug compound unless approved by the Investigator(s).					NO
04	History or presence of an abnormal ECG, which, in the Investigator(s) opinion, is clinically significant.					NO
05	History of alcoholism or drug addiction within 1 year prior to Study Entry; excessive alcohol consumption will be discouraged.					NO
06	Poor peripheral venous access.					NO
07	Donation of blood from 30 days prior to Screening through Week 24 (or Study Completion), inclusive, or of plasma from 2 weeks prior to Screening through Week 24 (or Study Completion), inclusive.					NO
08	Receipt of blood products within 2 months prior to Study Entry.					NO
09	Evidence of visible oral cancer, as found in an oral health examination or based on oral health questions at each visit.					NO
10	Any acute or chronic condition that, in the Investigator(s) opinion, would limit the subject's ability to complete and/or participate in this clinical study.					NO
11	Subject or a relative of the subject is or has ever been employed by the tobacco industry.					NO
12	Subject is an employee of Covance.					NO
13	Subject has participated in any other investigational study drug or product trial in which receipt of an investigational study drug or product occurred within 30 days prior to Check-in (inclusive).					NO

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 02-02-2007

Document #: R141898213

Section: Informed Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:08:12	
		Last Modification Time: 15-05-2007 14:12:50	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form		02-02-2007	

Section: Elig	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:08:12	
		Last Modification Time: 15-05-2007 14:13:28	
		Page number: 4	
Subject Eligibility			
Did the subject meet all of the inclusion criteria?		YES	
Did the subject have any of the exclusion criteria?		NO	
Criteria Type	Criteria Number	Deviation	Date Exemption Granted

Section: Patient_Rep_Outc	6 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:08:12	
		Last Modification Time: 15-05-2007 14:13:28	
		Page number: 4	
Patient Reported Outcome (PRO) Questionnaires			
Did the subject complete the Smoker Screening Questionnaire prior to any study procedures being performed?			Yes / No YES

Section: Demog	7 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:08:12	
		Last Modification Time: 15-05-2007 14:20:20	
		Page number: 5	
Demographics			
Date of Birth	Gender	Height	Subject Initials
	M	180.3	(b)
		xxx.x	
		Height Unit	Weight
		CM	106.8
			xxx.x
		Weight Unit	
		KG	
Ethnicity			

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 02-02-2007

Document #: R141898213

Section:	Demog	7 of 10
Hispanic or Latino?	Race	Race other
NO	WHITE	

Section:	Vital	8 of 10	Blank? N	Section Status: Entry Complete
Visit:	SCREENING	Section Date:	02-02-2007	
Entered By:	Tricia Hunt	Entry Time:	15-05-2007 14:08:12	
		Last Modification Time:	15-05-2007 14:20:20	
		Page number:	5	
VITAL SIGNS				
	Blood Pressure			Oral
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate
1012	119	77	74	15
				Temperature
				36.2
				xxx.x
Comments				Unit
				C

Section:	HdyL_Oral_Health	9 of 10	Blank? N	Section Status: Entry Complete
Visit:	SCREENING	Section Date:	02-02-2007	
Entered By:	Tricia Hunt	Entry Time:	15-05-2007 14:08:12	
		Last Modification Time:	15-05-2007 14:20:20	
		Page number:	5	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY				
		Oral Health		
		Questions		
Actual Time	HDYF Performed?	Performed?		Comments
NR	YES	YES		

Section:	Lab_Eval	10 of 10	Blank? N	Section Status: Entry Complete
Visit:	SCREENING	Section Date:	02-02-2007	
Entered By:	Tricia Hunt	Entry Time:	15-05-2007 14:08:12	
		Last Modification Time:	15-05-2007 14:20:20	
		Page number:	6	
Laboratory Evaluations				
Were the scheduled laboratory samples obtained?		YES	No, specify	
Requisition Number 1		N574619		
Requisition Number 2 (if applicable)				
Were there any clinically significant labs?		NO	(Yes, specify below)	
Requisition Number	Test Name	H/L	Lab ID	Lab Name

CRF Report for Study E6270229

Patient: 4003

CRF: Screening

Visit: SCREENING

Site: CP_001

Blank? N

Visit Date: 02-02-2007

Investigator: CP_001

CRF Page #: 2

Document #: R141898213

[Click here to navigate to response history for this CRF](#)

CRI Report for Study E6270229

Patient: 4003
CRF: Screening2
Visit: SCREENING

Site: CP_001
Blank? N
Visit Date: 02-02-2007

Investigator: CP_001
CRF Page #: 3
Document #: R141898913
CRF Status: Entry Complete

Entered By: Tricia Hunt
Discrepancies: Closed
Approval Status: Not Approved
Verification: Not Verified

Entry Time: 15-05-2007 14:20:23
Modification Time: 20-12-2007 10:26:58
Approval Time:
Verification Time:

Approver:
Verifier:

Comment:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:20:23	
		Last Modification Time: 15-05-2007 14:24:51	
		Page number: 6	
Urine Pregnancy Test			
Result			
N/A,			
MALE			
OR			
FEMA			
LE			

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:20:23	
		Last Modification Time: 15-05-2007 14:24:51	
		Page number: 6	
Urine Drug Screen			
Drug Screen Result			
NEG			

Section: Alcohol_Screen	3 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:20:23	
		Last Modification Time: 15-05-2007 14:24:51	
		Page number: 6	
Breathalyzer Alcohol Screen			
Breathalyzer Result			
NEG			

Section: Med_Hx	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	

CRF Report for Study E6270229

Patient: 4003
CRF: Screening2
Visit: SCREENING

Site: CP_001
Blank? N
Visit Date: 02-02-2007

Investigator: CP_001
CRF Page #: 3
Document #: R141898913

Section: Med_Hx	4 of 10		
Entered By: Tricia Hunt	Entry Time: 15-05-2007 14:20:23		
	Last Modification Time: 15-05-2007 14:24:51		
	Page number: 7		
Medical History			
Does the subject have any relevant medical history?		NO	
If so, list the specific diagnosis and/or procedure.			
System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing

Section: ECG	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Section Date: 02-02-2007		
Entered By: Tricia Hunt	Entry Time: 15-05-2007 14:20:23		
	Last Modification Time: 15-05-2007 14:24:51		
	Page number: 8		
12-LEAD ELECTROCARDIOGRAM REPORT			
Actual Time	Ventricular Heart Rate		
1020	59		
Cardiac Cycle Measurements			
PR Interval	QRS Duration	QT Interval	QTc Interval
188	90	408	404
ECG INTERPRETATION:			
NORMAL			
Comments (related to abnormal, CS findings only):			

Section: Usual_Brand_Cig	6 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Section Date: 02-02-2007		
Entered By: Tricia Hunt	Entry Time: 15-05-2007 14:20:23		
	Last Modification Time: 15-05-2007 14:24:51		
	Page number: 9		
USUAL BRAND CIGARETTE PACK DATA			
Usual Brand	Type	Length	
BRONCO	NON-MENTHOL	LONG 90-105MM	
How long have these been the subject's usual brand?			
Style	Pack	0	months
REGULAR	HARD	2	years

Section: Fic_Tar_Level	7 of 10	Blank? N	Section Status: Entry Complete
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CRF Report for Study E6270229

Patient: 4003

CRF: Screening2

Visit: SCREENING

Site: CP_001

Blank? N

Visit Date: 02-02-2007

Investigator: CP_001

CRF Page #: 3

Document #: R141898913

Section: Ftc_Tar_Level	7 of 10	Section Date: 02-02-2007
Visit: SCREENING		Entry Time: 15-05-2007 14:20:23
Entered By: Tricia Hunt		Last Modification Time: 18-12-2007 19:19:29
		Page number: 9
FTC TAR LEVEL OF USUAL BRAND		
FTC Tar Level (mg)		
13.0		

Section: Expired_Carbon_M	8 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:20:23	
		Last Modification Time: 15-05-2007 14:27:21	
		Page number: 10	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
0940	17	3.3	

Section: Best_Baseline_Sp	9 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:20:23	
		Last Modification Time: 18-12-2007 19:30:17	
		Page number: 10	
BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time	FEV 1 Predicted	FVC Predicted	
of FEV1/FVC Test	(%)	(%)	Comments
0955	4.61	6.39	114
Testing Position	STANDING		

Section: Irvs_Training	10 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 02-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:20:23	
		Last Modification Time: 15-05-2007 14:27:21	
		Page number: 10	
IVRS TRAINING			
Did Subject receive training on the Daily Call-In Diary (IVRS)?			
YES			

[Click here to navigate to response history for this CRF](#)

CRI Report for Study E6270229

Patient: 4003

CRF: Week-2

Visit: WEEK -2

Entered By: Tricia Hunt

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CP_001

Blank? N

Visit Date: 05-02-2007

Entry Time: 15-05-2007 14:28:10

Modification Time: 15-05-2007 14:28:51

Approval Time:

Verification Time:

Investigator: CP_001

CRF Page #: 4

Document #: R141899513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Usual_Brand_Coll	Blank? N	Section Status: Entry Complete
Visit: WEEK -2	Section Date: 05-02-2007	
Entered By: Tricia Hunt	Entry Time: 15-05-2007 14:28:10	
	Last Modification Time: 15-05-2007 14:28:51	
	Page number: 11	
USUAL BRAND	CIGARETTE COLLECTION TRAINING	
1. Did subject receive foam block?		YES
2. Did subject receive training on usual brand collection?		YES
3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?		YES

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 16-02-2007

Document #: R141899713

Entered By: Tricia Hunt

Entry Time: 15-05-2007 14:29:05

CRF Status: Entry Complete

Discrepancies: Closed

Modification Time: 07-01-2008 10:12:17

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pro_Questionnair	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05	
		Last Modification Time: 15-05-2007 14:44:57	
		Page number: 12A	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject	YES / NO	
16-02-2007	complete Smoker Routine Questionnaire PRIOR to any		
	study procedures being performed?	YES	

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05	
		Last Modification Time: 15-05-2007 14:44:57	
		Page number: 12A	
Drug Screen			
Date	Drug Screen Result		
16-02-2007	NEG		

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05	
		Last Modification Time: 15-05-2007 14:44:57	
		Page number: 12A	
Alcohol Screen			
Date	Breathalyzer Result		
16-02-2007	NEG		

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05	
		Last Modification Time: 15-05-2007 14:44:57	
		Page number: 12A	

CRI Report for Study E6270229

Patient: 4003

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CP_001

Blank? N

Visit Date: 16-02-2007

Investigator: CP_001

CRF Page #: 5

Document #: R141899713

Section: Preg_Test		4 of 11	
Pregnancy Test			
Date	Result		
16-02-2007	N/A, MALE OR FEMA LE		

Section: Urine_Coll		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007					
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05					
		Last Modification Time: 15-05-2007 14:44:57					
		Page number: 12A					
24-Hour Urine Collection							
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments	
SPOT URINE VOID	16-02-2007	1718	16-02-2007	1718	NA		
0 HOUR TO 24 HOURS	16-02-2007	1718	17-02-2007	1718	6500		

Section: Hdyf_Oral_Health		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007					
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05					
		Last Modification Time: 04-01-2008 15:58:07					
		Page number: 13.1					
HDYF? INQUIRY							
Date	Actual Time	HDYF Performed?		Comments			
17-02-2007	0730	YES					

Section: Vital		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007					
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05					
		Last Modification Time: 15-05-2007 14:44:57					
		Page number: 13.1					
VITAL SIGNS							
		Blood Pressure				Oral	
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit
16-02-2007	1658	118	77	59	15	ND	NA

CRF Report for Study E6270229

Patient: 4003

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CP_001

Blank? N

Visit Date: 16-02-2007

Investigator: CP_001

CRF Page #: 5

Document #: R141899713

Section: Vital	7 of 11	
Comments		xxx.x

Section: Oral_Health_Exam	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05	
		Last Modification Time: 15-08-2007 16:11:04	
		Page number: 13.1	
ORAL HEALTH EXAMINATION			
Date 16-02-2007			
Procedure	Relevant Findings?*	Findings	
ORAL HEALTH QUESTIONS PERFORMED	NO		
EVIDENCE OF LEUKOPLAKIA	NO		
OTHER ORAL KERATOSIS	NO		

Section: Phys_Exam	9 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05	
		Last Modification Time: 15-05-2007 14:44:57	
		Page number: 14.1	
PHYSICAL EXAMINATION			
Date 16-02-2007			
Code Number	Code	Relevant Findings?	Findings
01	GENERAL	NO	
02	SKIN	NO	
03	HEENT	NO	
04	MOUTH	NO	
05	NECK	NO	
06	THORAX/LUNG	NO	
07	CARDIO	NO	
08	ABDOMEN	NO	
09	MUSCULO	NO	
10	NEURO	NO	
11	LYMPH	NO	
12	OTHER	NO	

Section: Weight_Height	10 of 11	Blank? N	Section Status: Entry Complete
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CRF Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 16-02-2007

Document #: R141899713

Section: Weight_Height	10 of 11	Section Date: 16-02-2007
Visit: WEEK 0 (BASELINE)		Entry Time: 15-05-2007 14:29:05
Entered By: Tricia Hunt		Last Modification Time: 18-12-2007 20:09:36
		Page number: 14.1

Date	WEIGHT & HEIGHT	Unit	Height	Unit
16-02-2007	106.8	KG	ND	
	xxx.x		xxx.x	

Section: Lab_Eval	11 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 16-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:29:05	
		Last Modification Time: 04-01-2008 16:01:15	
		Page number: 15.1	

Laboratory Evaluations				
Date				
17-02-2007				
Were the scheduled laboratory samples obtained?	YES No, specify			
Requisition Number 1	N528277			
Requisition Number 2 (if applicable)				
Were there any clinically significant labs?	NO (Yes, specify below)			
17-02-2007				
	YES			
	N970629			
	NO			
Requisition Number	Test Name	H/L	Lab ID	Lab Name

[Click here to navigate to response history for this CRF](#)

CRI Report for Study E6270229

Patient: 4003

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Entered By: Tricia Hunt

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CP_001

Blank? N

Visit Date: 17-02-2007

Entry Time: 15-05-2007 14:44:58

Modification Time: 09-01-2008 15:39:49

Approval Time:

Verification Time:

Investigator: CP_001

CRF Page #: 5.1

Document #: R141902913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:44:58	
		Last Modification Time: 15-05-2007 15:00:12	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
17-02-2007	0730		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:44:58	
		Last Modification Time: 15-05-2007 15:00:12	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
17-02-2007	1243	24	4.4

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:44:58	
		Last Modification Time: 15-05-2007 15:00:12	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
17-02-2007	1247		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:44:58	
		Last Modification Time: 09-01-2008 15:38:33	
		Page number: 16.1	

CRI Report for Study E6270229

Patient: 4003

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CP_001

Blank? N

Visit Date: 17-02-2007

Investigator: CP_001

CRF Page #: 5.1

Document #: R141902913

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time							
Date	of FEV1/FVC	Testing			FVC		
	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
17-02-2007	1551	STANDI	5.22	115	6.97	124	
		NG					

Section:	Proventil_Admin	5 of 11	Blank?	N	Section Status:	Entry Complete
Visit:	WEEK 0 (BASELINE)		Section Date:	17-02-2007		
Entered By:	Tricia Hunt		Entry Time:	15-05-2007 14:44:58		
			Last Modification Time:	15-05-2007 15:00:12		
			Page number:	16.1		
PROVENTIL ADMINISTRATION						
		Actual Time				
		of Proventil				
Date	Administration		Amount Administered		Comments	
17-02-2007	1553		2 METERED PUFFS			

Section:	Post_Bronch_Spir	6 of 11	Blank?	N	Section Status:	Entry Complete
Visit:	WEEK 0 (BASELINE)		Section Date:	17-02-2007		
Entered By:	Tricia Hunt		Entry Time:	15-05-2007 14:44:58		
			Last Modification Time:	09-01-2008 15:39:49		
			Page number:	16.1		
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT						
	Actual Time					
	of FEV1/FVC	Testing				
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)
17-02-2007	1636	STANDING	5.80	127	7.19	128
						Comments

Section:	Unused_Usual_Bra	7 of 11	Blank?	N	Section Status:	Entry Complete
Visit:	WEEK 0 (BASELINE		Section Date:	17-02-2007		
Entered By:	Tricia Hunt		Entry Time:	15-05-2007 14:44:58		
			Last Modification Time:	15-05-2007 15:00:12		
			Page number:	17.1		
Unused Usual Brand Cigarette Pack Collection						
					Yes / No	
Date	Does Site have 5 unopened packs of subject's usual					
16-02-2007	brand cigarette to ship to CCLS?				YES	

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 17-02-2007

Document #: R141902913

Section: Usual_Brand_Butt	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:44:58	
		Last Modification Time: 15-05-2007 15:00:12	
		Page number: 17.1	

Usual Brand Cigarette Butt Collection					Number of Usual Brand Cigarette Butts Collected	Any Product Deviation?	If yes, number of butts other than usual brand:	Comments
Scheduled Collection Period:	Start Date	Start Time	Stop Date	Stop Time				
24 HOURS PRIOR TO CHECK-IN	15-02- 2007	1600	16-02-2007	1600	20	NO	NA	
24 HOURS IN-HOUSE	16-02- 2007	1709	17-02-2007	1710	27	NO	NA	

Section: Used_Butt_Measur	9 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-02-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 14:44:58	
		Last Modification Time: 15-05-2007 15:00:12	
		Page number: 18.1	

USUAL BRAND CIGARETTE BUTT MEASUREMENT																																						
Date	Scheduled Collection Period																																					
16-02-2007	24 HOURS PRIOR TO CHECK-IN																																					
		<table border="1"> <thead> <tr> <th>Cigarette Butt Number</th> <th>Cigarette Butt Measurement (mm)</th> </tr> </thead> <tbody> <tr><td>1</td><td>37</td></tr> <tr><td>2</td><td>39</td></tr> <tr><td>3</td><td>36</td></tr> <tr><td>4</td><td>40</td></tr> <tr><td>5</td><td>41</td></tr> <tr><td>6</td><td>47</td></tr> <tr><td>7</td><td>52</td></tr> <tr><td>8</td><td>41</td></tr> <tr><td>9</td><td>38</td></tr> <tr><td>10</td><td>40</td></tr> <tr><td>11</td><td>41</td></tr> <tr><td>12</td><td>49</td></tr> <tr><td>13</td><td>46</td></tr> <tr><td>14</td><td>40</td></tr> <tr><td>15</td><td>33</td></tr> <tr><td>16</td><td>41</td></tr> <tr><td>17</td><td>36</td></tr> </tbody> </table>	Cigarette Butt Number	Cigarette Butt Measurement (mm)	1	37	2	39	3	36	4	40	5	41	6	47	7	52	8	41	9	38	10	40	11	41	12	49	13	46	14	40	15	33	16	41	17	36
Cigarette Butt Number	Cigarette Butt Measurement (mm)																																					
1	37																																					
2	39																																					
3	36																																					
4	40																																					
5	41																																					
6	47																																					
7	52																																					
8	41																																					
9	38																																					
10	40																																					
11	41																																					
12	49																																					
13	46																																					
14	40																																					
15	33																																					
16	41																																					
17	36																																					

CRF Report for Study E6270229

Patient: 4003

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CP_001

Blank? N

Visit Date: 17-02-2007

Investigator: CP_001

CRF Page #: 5.1

Document #: R141902913

Section:	Used_Butt_Measur	9 of 11
	18	35
	19	39
	20	38

Section:	Used_Butt_Measur	10 of 11	Blank? N	Section Status:	Entry Complete
Visit:	WEEK 0 (BASELINE)		Section Date:	17-02-2007	
Entered By:	Tricia Hunt		Entry Time:	15-05-2007 14:44:58	
			Last Modification Time:	15-05-2007 15:00:12	
			Page number:	19.1	

USUAL BRAND CIGARETTE BUTT MEASUREMENT			
Scheduled Collection			
Date	Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
17-02-2007	24 HOURS IN-HOUSE	1	35
		2	30
		3	30
		4	32
		5	33
		6	35
		7	39
		8	38
		9	31
		10	39
		11	34
		12	35
		13	39
		14	36
		15	33
		16	37
		17	38
		18	34
		19	36
		20	35
		21	38
		22	41
		23	33
		24	33
		25	40
		26	40

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 17-02-2007

Document #: R141902913

	Section:	Used Butt Measur	10 of 11
		27	35

Section:	Randomization	11 of 11	Blank? N	Section Status:	Entry Complete
Visit:	WEEK 0 (BASELINE)		Section Date:	17-02-2007	
Entered By:	Tricia Hunt		Entry Time:	15-05-2007 14:44:58	
			Last Modification Time:	15-05-2007 15:00:12	
			Page number:	20.1	

RANDOMIZATION		
Date	Actual Time	Randomization Sequence
17-02-2007	1651	GROUP B

[Click here to navigate to response history for this CRF](#)

CRF Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 0 3baseline

Blank? N

CRF Page #: 5.2

Visit: WEEK 0 (BASELINE)

Visit Date: 17-02-2007

Document #: R141908813

Entered By: Tricia Hunt

Entry Time: 15-05-2007 15:00:13

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 18-01-2008 16:03:57

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Study_Prod_Dlspe	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)	Section Date: 17-02-2007	
Entered By: Tricia Hunt	Entry Time: 15-05-2007 15:00:13	
	Last Modification Time: 18-01-2008 16:03:57	
	Page number: 23.1	
STUDY PRODUCT DISPENSATION		
Date	Actual Time	Product Dispensed
17-02-2007	1721	SNUS
		Flavor
		FROST
		Amount Dispensed
		1

[Click here to navigate to response history for this CRF](#)

CRF Report for Study E6270229

Patient: 4003
CRF: Intercurrent_Ill
Visit: INTERCURRENT ILL
Entered By: Tricia Hunt
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CP_001
Blank? N
Visit Date: 16-02-2007
Entry Time: 18-12-2007 19:25:36
Modification Time: 18-12-2007 19:25:48
Approval Time:
Verification Time:

Investigator: CP_001
CRF Page #: 7
Document #: R170223513
CRF Status: Entry Complete
Approver:
Verifier:

Section: Ip_Findings		Blank? N		Section Status: Entry Complete				
Visit: INTERCURRENT ILL		Section Date: 16-02-2007						
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:25:36						
		Last Modification Time: 18-12-2007 19:25:48						
		Page number: 21						
Intercurrent Illness/Physical Findings								
Did the subject experience any intercurrent illness/findings from Screening to the first use of study product?								
NO								
Event No	Illness/Finding	Date	Onset Time	Resolved / Changed Date	Time	Severity	Relationship to Procedure	Action Taken

CRI Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 1	Blank? Y	CRF Page #: 8
Visit: WEEK 1	Visit Date: 01-03-2007	Document #: R141909813
Entered By: Tricia Hunt	Entry Time: 15-05-2007 15:02:20	CRF Status: Created
Discrepancies: None	Modification Time:	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment: Family illness, missed visit OK per Bobbi Jones		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 01-03-2007		
Entered By: Tricia Hunt	Entry Time: 15-05-2007 15:02:20		
Last Modification Time:			
Page number: 22			
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health	
		Questions	
		Performed?	
Actual Time	HDYF Performed?		Comments

Section: Vital	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 01-03-2007		
Entered By: Tricia Hunt	Entry Time: 15-05-2007 15:02:20		
Last Modification Time:			
Page number: 22			
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
			Respiratory Rate
			Temperature
			xxx.x
Comments			Unit

Section: Expired_Carbon_M	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 01-03-2007		
Entered By: Tricia Hunt	Entry Time: 15-05-2007 15:02:20		
Last Modification Time:			
Page number: 22			
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 01-03-2007		
Entered By: Tricia Hunt	Entry Time: 15-05-2007 15:02:20		
Last Modification Time:			

CRI Report for Study E6270229

Patient: 4003

CRF: Week 1

Visit: WEEK 1

Site: CP_001

Blank? Y

Visit Date: 01-03-2007

Investigator: CP_001

CRF Page #: 8

Document #: R141909813

Section: Unused_Study_Pro

4 of 5

Page number: 23

Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 1

Section Date: 01-03-2007

Entered By: Tricia Hunt

Entry Time: 15-05-2007 15:02:20

Last Modification Time:

Page number: 23

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRI Report for Study E6270229

Patient: 4003
 CRF: Week 2
 Visit: WEEK 2
 Entered By: Tricia Hunt
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CP_001
 Blank? N
 Visit Date: 01-03-2007
 Entry Time: 15-05-2007 15:04:13
 Modification Time: 18-01-2008 16:07:59
 Approval Time:
 Verification Time:

Investigator: CP_001
 CRF Page #: 9
 Document #: R141909913
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Hdyf_Oral_Health	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 01-03-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:04:13	
		Last Modification Time: 15-05-2007 15:07:42	
		Page number: 24	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
NR	YES	NO	ORAL HEATH QUESTIONS NOT PERFORMED IN ERROR

Section: Vital	2 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 01-03-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:04:13	
		Last Modification Time: 15-05-2007 15:07:42	
		Page number: 24	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
0912	117	74	84
			Respiratory Rate
			18
			Temperature
			36.7
			xxx.x
Unit			C
Comments			

Section: Expired_Carbon_M	3 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 01-03-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:04:13	
		Last Modification Time: 15-05-2007 15:07:42	
		Page number: 24	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
0907	12	2.5	

CRF Report for Study E6270229

Patient: 4003

CRF: Week 2

Visit: WEEK 2

Site: CP_001

Blank? N

Visit Date: 01-03-2007

Investigator: CP_001

CRF Page #: 9

Document #: R141909913

Section: Blood_Sampl_Cohb	4 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 01-03-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:04:13	
		Last Modification Time: 15-05-2007 15:07:42	
		Page number: 24	
Blood Sampling for %COHb			
Actual Time	Comments		
0916			

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 01-03-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:04:13	
		Last Modification Time: 15-05-2007 15:07:42	
		Page number: 25	
Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
SNUS	FROST	Packs	Individual Cigarettes / pouches
		0	0

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 01-03-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:04:13	
		Last Modification Time: 18-01-2008 16:07:59	
		Page number: 25	
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
NR	SNUS	FROST	1

[Click here to navigate to response history for this CRF](#)

CRI Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 4	Blank? N	CRF Page #: 10
Visit: WEEK 4	Visit Date: 15-03-2007	Document #: R141910313
Entered By: Tricia Hunt	Entry Time: 15-05-2007 15:07:43	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 15-05-2007 15:10:40	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pro_Questionnaire	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 15-03-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:07:43	
		Last Modification Time: 15-05-2007 15:10:40	
		Page number: 26	
<p align="center">PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p>			<p align="center">YES / NO</p> <p align="center">YES</p>

Section: Hdyf_Oral_Health	2 of 6	Blank? N	Section Status: Entry Complete								
Visit: WEEK 4		Section Date: 15-03-2007									
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:07:43									
		Last Modification Time: 15-05-2007 15:10:40									
		Page number: 26									
<p align="center">HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table border="0"> <tr> <td>Actual Time</td> <td>HDYF Performed?</td> <td>Oral Health Questions Performed?</td> <td>Comments</td> </tr> <tr> <td>NR</td> <td>YES</td> <td>NO</td> <td>ORAL HEALTH QUESTIONS NOT PERFORMED IN ERROR</td> </tr> </table>				Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments	NR	YES	NO	ORAL HEALTH QUESTIONS NOT PERFORMED IN ERROR
Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments								
NR	YES	NO	ORAL HEALTH QUESTIONS NOT PERFORMED IN ERROR								

Section: Vital	3 of 6	Blank? N	Section Status: Entry Complete																					
Visit: WEEK 4		Section Date: 15-03-2007																						
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:07:43																						
		Last Modification Time: 15-05-2007 15:10:40																						
		Page number: 26																						
<p align="center">VITAL SIGNS</p> <table border="0"> <tr> <td>Actual Time</td> <td colspan="2">Blood Pressure</td> <td>Pulse</td> <td>Respiratory Rate</td> <td>Oral Temperature</td> <td>Unit</td> </tr> <tr> <td>1409</td> <td>Systolic 126</td> <td>Diastolic 79</td> <td>75</td> <td>14</td> <td>36.4</td> <td>C</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td>xxx.x</td> <td></td> </tr> </table> <p>Comments</p>				Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit	1409	Systolic 126	Diastolic 79	75	14	36.4	C						xxx.x	
Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit																		
1409	Systolic 126	Diastolic 79	75	14	36.4	C																		
					xxx.x																			

CRI Report for Study E6270229

Patient: 4003

CRF: Week 4

Visit: WEEK 4

Site: CP_001

Blank? N

Visit Date: 15-03-2007

Investigator: CP_001

CRF Page #: 10

Document #: R141910313

Section: Expired_Carbon_M	4 of 6	Blank? N	Section Date: 15-03-2007	Section Status: Entry Complete
Visit: WEEK 4		Entry Time: 15-05-2007 15:07:43		
Entered By: Tricia Hunt		Last Modification Time: 15-05-2007 15:10:40		
		Page number: 26		

EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1410	18	3.5	

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Date: 15-03-2007	Section Status: Entry Complete
Visit: WEEK 4		Entry Time: 15-05-2007 15:07:43		
Entered By: Tricia Hunt		Last Modification Time: 15-05-2007 15:10:40		
		Page number: 27		

Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches
SNUS	FROST	0	0

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Date: 15-03-2007	Section Status: Entry Complete
Visit: WEEK 4		Entry Time: 15-05-2007 15:07:43		
Entered By: Tricia Hunt		Last Modification Time: 15-05-2007 15:10:40		
		Page number: 27		

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
NR	SNUS	FROST	2

Investigator: CP_001

CRF Page #: 11

Document #: R172381413

CRF Status: Created

Modification Time:

Approver:

Verifier:

Comment:

Section:	Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status:	Created				
Visit:	WEEK 6		Section Date:	29-03-2007					
Entered By:	Tricia Hunt		Entry Time:	09-01-2008 15:42:26					
			Last Modification Time:						
			Page number:	28					
<p>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <p>Oral Health Questions</p> <table border="1"> <thead> <tr> <th>Actual Time</th> <th>HDYF Performed?</th> <th>Performed?</th> <th>Comments</th> </tr> </thead> </table>						Actual Time	HDYF Performed?	Performed?	Comments
Actual Time	HDYF Performed?	Performed?	Comments						

Section:	Expired_Carbon_M	2 of 5	Blank?	Y	Section Status:	Created
Visit:	WEEK 6		Section Date:	29-03-2007		
Entered By:	Tricia Hunt		Entry Time:	09-01-2008 15:42:26		
			Last Modification Time:			
			Page number:	28		
	EXPIRED CARBON MONOXIDE					
	Actual Time	ECO Level (ppm)	%COHb	Comments		

Section:	Vital	3 of 5	Blank?	Y	Section Status:	Created
Visit:	WEEK 6		Section Date:	29-03-2007		
Entered By:	Tricia Hunt		Entry Time:	09-01-2008 15:42:26		
			Last Modification Time:			
			Page number:	28		
VITAL SIGNS						
	Blood Pressure			Oral		
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature xxx.x	Unit
Comments						

Section:	Unused_Study_Pro	4 of 5	Blank? Y	Section Status:	Created
Visit:	WEEK 6		Section Date:	29-03-2007	
Entered By:	Tricia Hunt		Entry Time:	09-01-2008 15:42:26	
			Last Modification Time:		

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 6

Blank? Y

CRF Page #: 11

Visit: WEEK 6

Visit Date: 29-03-2007

Document #: R172381413

Section:	Unused_Study_Pro	4 of 5	Page number:	29
Unused Study Product Returned				
Product Returned	Flavor	Amount Returned	Packs	Individual Cigarettes / pouches

Section:	Study_Prod_Dispe	5 of 5	Blank? Y	Section Status:	Created
Visit:	WEEK 6	Section Date:	29-03-2007	Entry Time:	09-01-2008 15:42:26
Entered By:	Tricia Hunt	Last Modification Time:	Page number:	29	
STUDY PRODUCT DISPENSATION					
Actual Time	Product Dispensed	Flavor	Amount Dispensed		

CRF Report for Study E6270229

Patient: 4003
 CRF: Week 8
 Visit: WEEK 8
 Entered By: Tricia Hunt
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CP_001
 Blank? N
 Visit Date: 10-04-2007
 Entry Time: 15-05-2007 15:11:01
 Modification Time: 15-05-2007 15:13:22
 Approval Time:
 Verification Time:

Investigator: CP_001
 CRF Page #: 13
 Document #: R141911113
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 10-04-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:11:01	
		Last Modification Time: 15-05-2007 15:13:22	
		Page number: 30	
PRO QUESTIONNAIRES With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO YES

Section: HDYF_Oral_Health	2 of 6	Blank? N	Section Status: Entry Complete								
Visit: WEEK 8		Section Date: 10-04-2007									
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:11:01									
		Last Modification Time: 15-05-2007 15:13:22									
		Page number: 30									
HDYF? / ORAL HEALTH QUESTIONS INQUIRY <table border="1"> <thead> <tr> <th>Actual Time</th> <th>HDYF Performed?</th> <th>Oral Health Questions Performed?</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>NR</td> <td>YES</td> <td>NO</td> <td>ORAL HEALTH QUESTIONS NOT PERFORMED IN ERROR</td> </tr> </tbody> </table>				Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments	NR	YES	NO	ORAL HEALTH QUESTIONS NOT PERFORMED IN ERROR
Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments								
NR	YES	NO	ORAL HEALTH QUESTIONS NOT PERFORMED IN ERROR								

Section: Vital	3 of 6	Blank? N	Section Status: Entry Complete												
Visit: WEEK 8		Section Date: 10-04-2007													
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:11:01													
		Last Modification Time: 15-05-2007 15:13:22													
		Page number: 30													
VITAL SIGNS <table border="1"> <thead> <tr> <th>Actual Time</th> <th>Blood Pressure</th> <th>Pulse</th> <th>Respiratory Rate</th> <th>Oral Temperature</th> <th>Unit</th> </tr> </thead> <tbody> <tr> <td>0737</td> <td>Systolic 127 Diastolic 77</td> <td>67</td> <td>16</td> <td>97.9 xxx.x</td> <td>F</td> </tr> </tbody> </table>				Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit	0737	Systolic 127 Diastolic 77	67	16	97.9 xxx.x	F
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit										
0737	Systolic 127 Diastolic 77	67	16	97.9 xxx.x	F										
Comments															

CRI Report for Study E6270229

Patient: 4003

CRF: Week 8

Visit: WEEK 8

Site: CP_001

Blank? N

Visit Date: 10-04-2007

Investigator: CP_001

CRF Page #: 13

Document #: R141911113

Section: Expired_Carbon_M	4 of 6	Blank? N	Section Status: Entry Complete	
Visit: WEEK 8		Section Date: 10-04-2007		
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:11:01		
		Last Modification Time: 15-05-2007 15:13:22		
		Page number: 30		
EXPIRED CARBON MONOXIDE				
Actual Time	ECO Level (ppm)	%COHb	Comments	
0740	13	2.7		

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete	
Visit: WEEK 8		Section Date: 10-04-2007		
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:11:01		
		Last Modification Time: 15-05-2007 15:13:22		
		Page number: 31		
Unused Study Product Returned				
Product Returned	Flavor	Amount Returned		
SNUS	FROST	Packs Individual Cigarettes / pouches		
		0 0		

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete	
Visit: WEEK 8		Section Date: 10-04-2007		
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:11:01		
		Last Modification Time: 15-05-2007 15:13:22		
		Page number: 31		
STUDY PRODUCT DISPENSATION				
Actual Time	Product Dispensed	Flavor	Amount Dispensed	
NR	SNUS	FROST	3	

CRI Report for Study E6270229

Patient: 4003
 CRF: Week 10
 Visit: WEEK 10
 Entered By: Tricia Hunt
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CP_001
 Blank? N
 Visit Date: 27-04-2007
 Entry Time: 15-05-2007 15:13:23
 Modification Time: 15-05-2007 15:15:04
 Approval Time:
 Verification Time:

Investigator: CP_001
 CRF Page #: 14
 Document #: R141911813
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: HDYF_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 27-04-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:13:23	
		Last Modification Time: 15-05-2007 15:15:04	
		Page number: 32	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
0853	YES	YES	

Section: Expired_Carbon_M	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 27-04-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:13:23	
		Last Modification Time: 15-05-2007 15:15:04	
		Page number: 32	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
0902	12	2.5	

Section: Vital	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 27-04-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:13:23	
		Last Modification Time: 15-05-2007 15:15:04	
		Page number: 32	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
0900	Systolic Diastolic	61	16
			Oral Temperature
			97.1
			xxx.x
Comments			Unit F

Section: Unused_Study_Pro	4 of 5	Blank? N	Section Status: Entry Complete
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CRI Report for Study E6270229

Patient: 4003

CRF: Week 10

Visit: WEEK 10

Site: CP_001

Blank? N

Visit Date: 27-04-2007

Investigator: CP_001

CRF Page #: 14

Document #: R141911813

Section: Unused_Study_Pro	4 of 5	Section Date: 27-04-2007
Visit: WEEK 10		Entry Time: 15-05-2007 15:13:23
Entered By: Tricia Hunt		Last Modification Time: 15-05-2007 15:15:04
Page number: 33		
Unused Study Product Returned		
Product Returned	Flavor	Amount Returned
SNUS	FROST	Packs Individual Cigarettes / pouches
		0 0

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 27-04-2007	
Entered By: Tricia Hunt		Entry Time: 15-05-2007 15:13:23	
		Last Modification Time: 15-05-2007 15:15:04	
Page number: 33			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
0909	SNUS	FROST	2

CRI Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 12	Blank? N	CRF Page #: 15
Visit: WEEK 12	Visit Date: 11-05-2007	Document #: R170224113
Entered By: Tricia Hunt	Entry Time: 18-12-2007 19:32:28	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 04-01-2008 16:02:01	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:32:28	
		Last Modification Time: 18-12-2007 19:48:40	
		Page number: 34	

PRO QUESTIONNAIRES		
Date		YES / NO
11-05-2007	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:32:28	
		Last Modification Time: 18-12-2007 19:48:40	
		Page number: 34	

Drug Screen	
Date	Drug Screen Result
11-05-2007	POS

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:32:28	
		Last Modification Time: 18-12-2007 19:48:40	
		Page number: 34	

Alcohol Screen	
Date	Breathalyzer Result
11-05-2007	NEG

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:32:28	
		Last Modification Time: 18-12-2007 19:48:40	
		Page number: 34	

CRI Report for Study E6270229

Patient: 4003

CRF: Week 12

Visit: WEEK 12

Site: CP_001

Blank? N

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 15

Document #: R170224113

Section: Preg_Test		4 of 11	
Pregnancy Test			
Date	Result		
11-05-2007	N/A, MALE OR FEMA LE		

Section: Urine_Coll		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 12		Section Date: 11-05-2007		Entry Time: 18-12-2007 19:32:28			
Entered By: Tricia Hunt		Last Modification Time: 18-12-2007 19:48:40		Page number: 34			
24-Hour Urine Collection							
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments	
SPOT URINE VOID	11-05-2007	1628	11-05-2007	1628	NA		
0 HOUR TO 24 HOURS	11-05-2007	1628	NA	NA	NA		

Section: Hdyf_Oral_Health		6 of 11		Blank? Y		Section Status: Entry Complete	
Visit: WEEK 12		Section Date: 11-05-2007		Entry Time: 18-12-2007 19:32:28			
Entered By: Tricia Hunt		Last Modification Time: 04-01-2008 16:02:01		Page number: 35			
HDYF? INQUIRY							
Date	Actual Time	HDYF Performed?			Comments		

Section: Vital		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 12		Section Date: 11-05-2007		Entry Time: 18-12-2007 19:32:28			
Entered By: Tricia Hunt		Last Modification Time: 18-12-2007 19:48:40		Page number: 35			
VITAL SIGNS							
Blood Pressure							
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
11-05-2007	1638	107	70	65	16	97.6	F
xxx.x							

CRI Report for Study E6270229

Patient: 4003

CRF: Week 12

Visit: WEEK 12

Site: CP_001

Blank? N

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 15

Document #: R170224113

Section: Vital	7 of 11	
Comments		

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 18-12-2007 19:32:28		
Last Modification Time:			
Page number: 35			
ORAL HEALTH EXAMINATION			
Date	Procedure	Relevant Findings?*	Findings

Section: Phys_Exam	9 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 18-12-2007 19:32:28		
Last Modification Time:			
Page number: 36			
PHYSICAL EXAMINATION			
Date	Code Number	Code	Relevant Findings?
			Findings

Section: Weight_Height	10 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 18-12-2007 19:32:28		
Last Modification Time:			
Page number: 36			
WEIGHT & HEIGHT			
Date	Weight	Unit	Height
	xxx.x		xxx.x

Section: Lab_Eval	11 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 18-12-2007 19:32:28		
Last Modification Time:			
Page number: 37			
Laboratory Evaluations			
Date	Were the scheduled laboratory samples obtained?		
	No, specify		

CRI Report for Study E6270229

Patient: 4003

CRF: Week 12

Visit: WEEK 12

Site: CP_001

Blank? N

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 15

Document #: R170224113

Section: Lab_Eval		11 of 11		
Requisition Number 1				
Requisition Number 2 (if applicable)				
Were there any clinically significant labs?				
(Yes, specify below)				
Requisition Number	Test Name	H/L	Lab ID	Lab Name

[Click here to navigate to response history for this CRF](#)

CRI Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 12(2)	Blank? Y	CRF Page #: 16
Visit: WEEK 12	Visit Date: 11-05-2007	Document #: R170224213
Entered By: Tricia Hunt	Entry Time: 18-12-2007 19:48:46	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	

Comment: Subject failed drug screen at check-in and was withdrawn from the study.

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:48:46	
		Last Modification Time:	
		Page number: 37	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:48:46	
		Last Modification Time:	
		Page number: 37	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
			Comments

Section: Blood_Sampl_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:48:46	
		Last Modification Time:	
		Page number: 37	
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:48:46	
		Last Modification Time:	
		Page number: 38	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
	Actual Time		

CRI Report for Study E6270229

Patient: 4003

CRF: Week 12(2)

Visit: WEEK 12

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 16

Document #: R170224213

Section:	Pre_Bronch_Spir	4 of 11						
Date	of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments	

Section:	Proventil_Admin	5 of 11	Blank? Y	Section Date: 11-05-2007	Section Status: Created			
Visit:	WEEK 12			Entry Time: 18-12-2007 19:48:46				
Entered By:	Tricia Hunt			Last Modification Time:				
				Page number: 38				
PROVENTIL ADMINISTRATION								
	Actual Time of Proventil Administration		Amount Administered				Comments	
Date								

Section:	Post_Bronch_Spir	6 of 11	Blank? Y	Section Date: 11-05-2007	Section Status: Created			
Visit:	WEEK 12			Entry Time: 18-12-2007 19:48:46				
Entered By:	Tricia Hunt			Last Modification Time:				
				Page number: 38				
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT								
	Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments	
Date								

Section:	Used_Study_Tobac	7 of 11	Blank? Y	Section Date: 11-05-2007	Section Status: Created			
Visit:	WEEK 12			Entry Time: 18-12-2007 19:48:46				
Entered By:	Tricia Hunt			Last Modification Time:				
				Page number: 39				
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION								
Scheduled Collection Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Tobacco-Heating Cigarettes Collected	Weight of Cigarettes Collected (g)	Any Product Deviation?	If yes, # of other Brand
								Comments

Section:	Used_Study_Snus	8 of 11	Blank? Y	Section Date: 11-05-2007	Section Status: Created			
Visit:	WEEK 12			Entry Time: 18-12-2007 19:48:46				
Entered By:	Tricia Hunt							

CRI Report for Study E6270225

Patient: 4003

CRF: Week 12(2)

Visit: WEEK 12

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 16

Document #: R170224213

Section:	Used_Study_Snus	8 of 11
Last Modification Time:		
Page number: 40		

USED STUDY SNUS COLLECTION								
Scheduled Collection	Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Pouches Collected	Any Product Deviation?	If Yes, # of other brand: Comments

Section:	Used_Study_Burn	9 of 11	Blank? Y	Section Status: Created
Visit:	WEEK 12	Section Date:	11-05-2007	
Entered By:	Tricia Hunt	Entry Time:	18-12-2007 19:48:46	
		Last Modification Time:		
		Page number:	41	

USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION								
Scheduled Collection	Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Tobacco-Burning Cigarettes Collected	Any Product Deviation?	If Yes, # of other brand: Comments

Section:	Used_Butt_Measur	10 of 11	Blank? Y	Section Status: Created
Visit:	WEEK 12	Section Date:	11-05-2007	
Entered By:	Tricia Hunt	Entry Time:	18-12-2007 19:48:46	
		Last Modification Time:		
		Page number:	42	

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT				
Date	Scheduled Collection	Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)

Section:	Used_Butt_Measur	11 of 11	Blank? Y	Section Status: Created
Visit:	WEEK 12	Section Date:	11-05-2007	
Entered By:	Tricia Hunt	Entry Time:	18-12-2007 19:48:46	
		Last Modification Time:		
		Page number:	43	

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT				
Date	Scheduled Collection	Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 12(3)

Blank? Y

CRF Page #: 17

Visit: WEEK 12

Visit Date: 11-05-2007

Document #: R170224313

Entered By: Tricia Hunt

Entry Time: 18-12-2007 19:48:59

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment: Subject failed drug test and was withdrawn from study per protocol.

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:48:59	
		Last Modification Time:	
		Page number: 44	
Unused Study Product Returned			
Date	Actual Time	Product Returned	Flavor
			Amount Returned
			Packs Individual Cigarettes / pouches

Section: Study_Prod_Dispe	2 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 18-12-2007 19:48:59	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed

CRI Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 14	Blank? Y	CRF Page #: 18
Visit: WEEK 14	Visit Date: 11-05-2007	Document #: R171773513
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:02:58	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: HDYf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:02:58	
		Last Modification Time:	
		Page number: 45	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
		Performed?	
Actual Time	HDYF Performed?		Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:02:58	
		Last Modification Time:	
		Page number: 45	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:02:58	
		Last Modification Time:	
		Page number: 45	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Oral Temperature
			xxx.x
Comments			Unit

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:02:58	
		Last Modification Time:	

CRI Report for Study E6270229

Patient: 4003

CRF: Week 14

Visit: WEEK 14

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 18

Document #: R171773513

Section:	Unused_Study_Pro	4 of 5	Page number: 46	
Unused Study Product Returned				
Product Returned	Flavor	Amount Returned Packs Individual Cigarettes / pouches		

Section:	Study_Prod_Dispe	5 of 5	Blank? Y	Section Status: Created
Visit:	WEEK 14	Section Date: 11-05-2007		
Entered By:	Tricia Hunt	Entry Time: 04-01-2008 16:02:58		
		Last Modification Time:		
		Page number: 46		
STUDY PRODUCT DISPENSATION				
Actual Time	Product Dispensed	Flavor	Amount Dispensed	

Investigator: CP_001

CRF Page #: 19

Document #: R171773613

CRF Status: Created

Modification Time:

Approver:

Verifier:

Comment:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:07	
		Last Modification Time:	
		Page number: 47	
		PRO QUESTIONNAIRES	
		With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?	YES / NO

Section:	Hdyf_Oral_Health	2 of 6	Blank?	Y	Section Status:	Created
Visit:	WEEK 16		Section Date:	11-05-2007		
Entered By:	Tricia Hunt		Entry Time:	04-01-2008 16:03:07		
			Last Modification Time:			
			Page number:	47		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY						
			Oral Health Questions Performed?			
	Actual Time	HDYF Performed?				Comments

Section:	Vital	3 of 6	Blank?	Y	Section Status:	Created
Visit:	WEEK 16		Section Date:	11-05-2007		
Entered By:	Tricia Hunt		Entry Time:	04-01-2008 16:03:07		
			Last Modification Time:			
			Page number:	47		
VITAL SIGNS						
	Blood Pressure			Oral		
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit
					xxx.x	
Comments						

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 11-05-2007	

CRI Report for Study E6270229

Patient: 4003

CRF: Week 16

Visit: WEEK 16

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 19

Document #: R171773613

Section: Expired_Carbon_M	4 of 6		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:07		
Last Modification Time:			
Page number: 47			
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	5 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:07		
Last Modification Time:			
Page number: 48			
Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe	6 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:07		
Last Modification Time:			
Page number: 48			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRI Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 18	Blank? Y	CRF Page #: 20
Visit: WEEK 18	Visit Date: 11-05-2007	Document #: R171773713
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:19	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:19	
		Last Modification Time:	
		Page number: 49	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:19	
		Last Modification Time:	
		Page number: 49	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:19	
		Last Modification Time:	
		Page number: 49	
VITAL SIGNS			
Actual Time	Blood Pressure		Oral
	Systolic	Diastolic	Temperature
		Pulse	xxx.x
		Respiratory Rate	Unit
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:19	
		Last Modification Time:	

CRI Report for Study E6270229

Patient: 4003

CRF: Week 18

Visit: WEEK 18

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 20

Document #: R171773713

Section: Unused_Study_Pro

4 of 5

Page number: 50

Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 18

Section Date: 11-05-2007

Entered By: Tricia Hunt

Entry Time: 04-01-2008 16:03:19

Last Modification Time:

Page number: 50

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 20	Blank? Y	CRF Page #: 21
Visit: WEEK 20	Visit Date: 11-05-2007	Document #: R171773813
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:29	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:29		
	Last Modification Time:		
	Page number: 51		
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: HDYf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:29		
	Last Modification Time:		
	Page number: 51		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
	Oral Health Questions		
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:29		
	Last Modification Time:		
	Page number: 51		
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Oral Temperature
	Systolic	Diastolic	xxx.x
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20	Section Date: 11-05-2007		

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 20

Blank? Y

CRF Page #: 21

Visit: WEEK 20

Visit Date: 11-05-2007

Document #: R171773813

Section: Expired_Carbon_M	4 of 6		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:29		
Last Modification Time:			
Page number: 51			
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	5 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:29		
Last Modification Time:			
Page number: 52			
Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe	6 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:29		
Last Modification Time:			
Page number: 52			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRI Report for Study E6270229

Patient: 4003

CRF: Week 22

Visit: WEEK 22

Entered By: Tricia Hunt

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Entry Time: 04-01-2008 16:03:37

Modification Time:

Approval Time:

Verification Time:

Investigator: CP_001

CRF Page #: 22

Document #: R171773913

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:37	
		Last Modification Time:	
		Page number: 53	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:37	
		Last Modification Time:	
		Page number: 53	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:37	
		Last Modification Time:	
		Page number: 53	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:37	
		Last Modification Time:	

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 22

Blank? Y

CRF Page #: 22

Visit: WEEK 22

Visit Date: 11-05-2007

Document #: R171773913

Section: Unused_Study_Pro	4 of 5	Page number: 54
Unused Study Product Returned		
Product Returned	Flavor	Amount Returned Packs Individual Cigarettes / pouches

Section: Study_Prod_Dispe	5 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:37	
		Last Modification Time:	
		Page number: 54	
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRI Report for Study E6270229

Patient: 4003

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Tricia Hunt

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Entry Time: 04-01-2008 16:03:45

Modification Time:

Approval Time:

Verification Time:

Investigator: CP_001

CRF Page #: 23

Document #: R171774013

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	
		Page number: 55	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES / NO	

Section: Urine_Drug	2 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	
		Page number: 55	
Drug Screen			
Date	Drug Screen Result		

Section: Alcohol_Screen	3 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	
		Page number: 55	
Alcohol Screen			
Date	Breathalyzer Result		

Section: Preg_Test	4 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	
		Page number: 55	
Pregnancy Test			

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 11-05-2007

Document #: R171774013

Section: Preg_Test	4 of 12	
Date	Result	

Section: Urine_Coll	5 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	
		Page number: 55	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
			Comments

Section: ECG	6 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	
		Page number: 56	
12-LEAD ELECTROCARDIOGRAM REPORT			
Actual Time	Ventricular Heart Rate		
	Cardiac Cycle Measurements		
PR Interval	QRS Duration	QT Interval	QTc Interval
ECG INTERPRETATION:			
Comments (related to abnormal, CS findings only):			

Section: Hdyf_Oral_Health	7 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	
		Page number: 57	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Date	Actual Time	HDYF Performed?	Oral Health Questions Performed?
			Comments

Section: Vital	8 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007	
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45	
		Last Modification Time:	

CRI Report for Study E6270229

Patient: 4003

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 23

Document #: R171774013

Section: Vital		8 of 12		Page number: 57			
VITAL SIGNS							
		Blood Pressure				Oral	
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature xxx.x	Unit
Comments							

Section: Oral_Health_Exam		9 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007					
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45					
		Last Modification Time:					
		Page number: 57					
ORAL HEALTH EXAMINATION							
Date	Procedure			Relevant Findings?*		Findings	

Section: Phys_Exam		10 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007					
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45					
		Last Modification Time:					
		Page number: 58					
PHYSICAL EXAMINATION							
Date	Code Number	Code	Relevant Findings?			Findings	

Section: Weight_Height		11 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007					
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45					
		Last Modification Time:					
		Page number: 58					
WEIGHT & HEIGHT							
Date	Weight xxx.x	Unit	Height xxx.x	Unit			

Section: Lab_Eval		12 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 11-05-2007					
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:03:45					

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 11-05-2007

Document #: R171774013

Section: Lab_Eval

12 of 12

Last Modification Time:

Page number: 59

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

No, specify

Requisition Number 1

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

CRI Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Week 24-2 (Eos)	Blank? Y	CRF Page #: 24
Visit: WEEK 24 (EOS)	Visit Date: 11-05-2007	Document #: R171774113
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:54	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:54		
	Last Modification Time:		
	Page number: 59		
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:54		
	Last Modification Time:		
	Page number: 59		
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
			Comments

Section: Blood_Sampl_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:54		
	Last Modification Time:		
	Page number: 59		
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 11-05-2007		
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:03:54		
	Last Modification Time:		
	Page number: 60		
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
	Actual Time		

CRI Report for Study E6270229

Patient: 4003

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Investigator: CP_001

CRF Page #: 24

Document #: R171774113

Section: Pre_Bronch_Spir	4 of 11							
Date	of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments	

Section: Proventil_Admin	5 of 11	Blank? Y	Section Date: 11-05-2007	Entry Time: 04-01-2008 16:03:54	Last Modification Time:	Page number: 60	Section Status: Created
Entered By: Tricia Hunt							
PROVENTIL ADMINISTRATION							
Date	Actual Time of Proventil Administration	Amount Administered	Comments				

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Date: 11-05-2007	Entry Time: 04-01-2008 16:03:54	Last Modification Time:	Page number: 60	Section Status: Created
Entered By: Tricia Hunt							
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
Date	Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments

Section: Used_Study_Tobac	7 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 11-05-2007	Entry Time: 04-01-2008 16:03:54	
Entered By: Tricia Hunt	Last Modification Time:	Page number: 61	
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION			
Scheduled Collection		Number of Study Tobacco-Heating	
Timepoint	Start Date	Start Time	Stop Date
			Stop Time
		Cigarettes Collected	Weight of Cigarettes Collected (g)
			Any Product Deviation?
			If yes, # of other Brand
			Comments

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Date: 11-05-2007	Entry Time: 04-01-2008 16:03:54			Section Status: Created
Entered By: Tricia Hunt							

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Week 24-2 (Eos)

Blank? Y

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 11-05-2007

Document #: R171774113

Section:	Used_Study_Snus	8 of 11						
Last Modification Time:								
Page number: 62								
USED STUDY SNUS COLLECTION								
Scheduled Collection								
Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Pouches Collected	Any Product Deviation?	If Yes, # of other brand:	Comments

Section:	Used_Study_Burn	9 of 11	Blank? Y		Section Status: Created			
Visit:	WEEK 24 (EOS)	Section Date:		11-05-2007				
Entered By:	Tricia Hunt	Entry Time:		04-01-2008 16:03:54				
Last Modification Time:								
Page number: 63								
USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION								
Scheduled Collection								
Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Tobacco-Burning Cigarettes Collected	Any Product Deviation?	If Yes, # of other brand:	Comments

Section:	Used_Butt_Measur	10 of 11	Blank? Y		Section Status: Created			
Visit:	WEEK 24 (EOS)	Section Date:		11-05-2007				
Entered By:	Tricia Hunt	Entry Time:		04-01-2008 16:03:54				
Last Modification Time:								
Page number: 64								
USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT								
Date	Scheduled Collection	Period	Cigarette Butt Number			Cigarette Butt Measurement (mm)		

Section:	Used_Butt_Measur	11 of 11	Blank? Y		Section Status: Created			
Visit:	WEEK 24 (EOS)	Section Date:		11-05-2007				
Entered By:	Tricia Hunt	Entry Time:		04-01-2008 16:03:54				
Last Modification Time:								
Page number: 65								
USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT								
Date	Scheduled Collection	Period	Cigarette Butt Number			Cigarette Butt Measurement (mm)		

CRI Report for Study E6270229

Patient: 4003

CRF: Week 24-3

Visit: WEEK 24 (EOS)

Entered By: Tricia Hunt

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CP_001

Blank? Y

Visit Date: 11-05-2007

Entry Time: 04-01-2008 16:04:04

Modification Time:

Approval Time:

Verification Time:

Investigator: CP_001

CRF Page #: 25

Document #: R171774213

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 11-05-2007	
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:04:04	
	Last Modification Time:	
	Page number: 65A	

Unused Study Product Returned				Amount Returned	
Date	Actual Time	Product Returned	Flavor	Packs	Individual Cigarettes / pouches

CRI Report for Study E6270229

Patient: 4003
CRF: Precon_Med
Visit: PRECON_MEDS
Entered By: Tricia Hunt
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CP_001
Blank? N
Visit Date: 15-02-2007
Entry Time: 18-12-2007 20:03:15
Modification Time: 20-12-2007 10:26:35
Approval Time:
Verification Time:

Investigator: CP_001
CRF Page #: 26
Document #: R170224613
CRF Status: Entry Complete
Approver:
Verifier:

Section: Pre_Conmed	Blank? N	Section Status: Entry Complete
Visit: PRECON_MEDS	Section Date: 15-02-2007	
Entered By: Tricia Hunt	Entry Time: 18-12-2007 20:03:15	
	Last Modification Time: 18-12-2007 20:06:04	
	Page number: 66	

Previous and Concomitant Medications									
Has the subject taken any medications prior to the first use of study product and/or during the study as restricted by the protocol?									
Dose /									
Seq #	Drug Name	Indication	Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing
1	IBUPROPHEN	UNK	400 MG	PO		PRN		15-02-2007	ONGOING
2	OXYCODONE	BACK PAIN	5 MG	PO		PRN		01-05-2007	06-05-2007

CRF Report for Study E6270229

Patient: 4003

CRF: AE

Visit: AE

Entered By: Tricia Hunt

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CP_001

Blank? N

Visit Date: 11-05-2007

Entry Time: 04-01-2008 16:04:10

Modification Time: 07-01-2008 10:12:17

Approval Time:

Verification Time:

Investigator: CP_001

CRF Page #: 27

Document #: R171774313

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ae_Med		Blank? N		Section Status: Entry Complete	
Visit: AE		Section Date: 11-05-2007			
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:04:10			
		Last Modification Time: 04-01-2008 16:45:26			
		Page number: 67			

Adverse Events											
Did the subject experience any adverse events? YES											
Event No.	Adverse Event	Onset Date	Onset Time	Resolved/Changed Date	Resolved/Changed Time	Serious Event?	Severity	Relationship to Product	Relationship to Procedure	Action Taken	Outcome to Date
1	BACK PAIN	01-05-2007	UNK	06-05-2007	UNK	NO	MODE RATE	NOT RELATE D	NOT RELATE D	DRUG THERAP Y	RECOVERED

[Click here to navigate to response history for this CRF](#)

[Click here to navigate to discrepancy detail for this CRF](#)

CRF Report for Study E6270229

Patient: 4003	Site: CP_001	Investigator: CP_001
CRF: Ecg_Unscheduled	Blank? Y	CRF Page #: 28
Visit: ECG_UNSCHEDED	Visit Date: 00-00-	Document #: R171774413
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:04:27	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: ECG	Blank? Y	Section Status: Created						
Visit: ECG_UNSCHEDED	Section Date: 00-00-							
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:04:27							
	Last Modification Time:							
	Page number: 68							
UNSCHEDULED 12-LEAD ELECTROCARDIOGRAM REPORT								
		Ventricular	Cardiac Cycle Measurements					
Date	Actual Time	Heart Rate	PR Interval	QRS Duration	QT Interval	QTc Interval	Interpretation	Comments

CRF Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Lab_Unscheduled

Blank? Y

CRF Page #: 29

Visit: LAB_UNSCHEDED

Visit Date: 00-00-

Document #: R171774513

Entered By: Tricia Hunt

Entry Time: 04-01-2008 16:04:35

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Lab_Eval	Blank? Y	Section Status: Created
Visit: LAB_UNSCHEDED	Section Date: 00-00-	
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:04:35	
	Last Modification Time:	
	Page number: 69	

Unscheduled Laboratory Evaluations							
Date	Requisition Number	Clinically Significant?	Test Name	High(H)/Low(L)	If Clinically Significant, Specify Lab ID	Lab Name	Comments

CRI Report for Study E6270225

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Vital_Unscheduled

Blank? Y

CRF Page #: 30

Visit: VITAL_UNSCHEDED

Visit Date: 00-00-

Document #: R171774713

CRF Status: Created

Entered By: Tricia Hunt

Entry Time: 04-01-2008 16:04:50

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Vital	Blank? Y	Section Status: Created
Visit: VITAL_UNSCHEDED	Section Date: 00-00-	
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:04:50	
	Last Modification Time:	
	Page number: 70	

UNSCHEDULED VITAL SIGNS								
Date	Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit	Comments
		Systolic	Diastolic			Temperature		
						xxx.x		

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Stdy_Prdt_Dis_Unschedule

Blank? Y

CRF Page #: 31

Visit: STDY_PRDT_UNSCHE

Visit Date: 00-00-

Document #: R171774813

Entered By: Tricia Hunt

Entry Time: 04-01-2008 16:04:55

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Study_Prod_Dispe	Blank? Y	Section Status: Created			
Visit: STDY_PRDT_UNSCHE	Section Date: 00-00-				
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:04:55				
	Last Modification Time:				
	Page number: 71				
UNSCHEDULED STUDY PRODUCT DISPENSATION					
Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed	Comments

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Expired_Co2_Unscheduled

Blank? Y

CRF Page #: 32

Visit: EXPIRED_CO2_UNSC

Visit Date: 00-00-

Document #: R171774913

Entered By: Tricia Hunt

Entry Time: 04-01-2008 16:05:00

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Expired_Carbon_M	Blank? Y	Section Status: Created
Visit: EXPIRED_CO2_UNSC	Section Date: 00-00-	
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:05:00	
	Last Modification Time:	
	Page number: 72	
	UNSCHEDULED EXPIRED CARBON MONOXIDE	
Date	Actual Time	ECO Level (ppm)
		%COHb
		Comments

CRI Report for Study E6270229

Patient: 4003 Site: CP_001 Investigator: CP_001
CRF: Oral_Health_Unscheduled Blank? Y CRF Page #: 33
Visit: ORAL_HEALTH_UNSC Visit Date: 00-00- Document #: R171775013
Entered By: Tricia Hunt Entry Time: 04-01-2008 16:05:04 CRF Status: Created
Discrepancies: None Modification Time:
Approval Status: Not Approved Approval Time:
Verification: Not Verified Verification Time:
Comment: Approver:
Verifier:

Section: Oral_Health_Exam	Blank? Y	Section Status: Created
Visit: ORAL_HEALTH_UNSC	Section Date: 00-00-	
Entered By: Tricia Hunt	Entry Time: 04-01-2008 16:05:04	
	Last Modification Time:	
	Page number: 73	

UNSCHEDULED ORAL HEALTH EXAMINATION				
Date	Actual Time	Code	Relevant Findings?	Comment

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Spirometry_Unscheduled

Blank? Y

CRF Page #: 34

Visit: SPIRO_TEST_UNSCH

Visit Date: 00-00-

Document #: R171775113

Entered By: Tricia Hunt

Entry Time: 04-01-2008 16:05:08

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pre_Bronch_Spir		Blank? Y		Section Status: Created	
Visit: SPIRO_TEST_UNSCH		Section Date: 00-00-			
Entered By: Tricia Hunt		Entry Time: 04-01-2008 16:05:08			
		Last Modification Time:			
		Page number: 74			
UNSCHEDULED SPIROMETRY TEST RESULT					
	Actual Time of FEV1/FVC Test	Testing Position	Timepoint based on Proventil Administration	Proventil Administration (and time of Administration)	(Time)
Date				FEV1 Predicted (%)	FEV1 L
				FVC Predicted (%)	FVC L
					Comments

CRI Report for Study E6270229

Patient: 4003

Site: CP_001

Investigator: CP_001

CRF: Study_Completion

Blank? N

CRF Page #: 35

Visit: STUDY_COMP

Visit Date: 11-05-2007

Document #: R152748413

Entered By: Tricia Hunt

Entry Time: 15-08-2007 15:53:56

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 15-08-2007 15:57:55

Approval Status: Not Approved

Approval Time:


Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Study_Comp	Blank? N	Section Status: Entry Complete
Visit: STUDY_COMP	Section Date: 11-05-2007	
Entered By: Tricia Hunt	Entry Time: 15-08-2007 15:53:56	
	Last Modification Time: 15-08-2007 15:57:55	
	Page number: 75	
<p>Study Completion</p> <p>Did the subject complete the study? NO</p> <p>Date the subject completed OR withdrew from the study: 11-05-2007</p> <p>Reason for Withdrawal OTH</p> <p>Specify SUBJECTS DRUG SCREEN WAS POSITIVE AT WEEK 12 CHECK IN.</p> <p>Investigator Comments</p> <p>Principal Investigator  Date 21 JAN 2008</p>		

Covance CLS

Marietta Henry, M.D., Director
 8211 SciCor Drive - Indianapolis, IN 46214-2985
 Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N574619

Page 1 of 3

INVESTIGATOR: (J14315)

Keith Klatt, M.D.
 c/o Heather Aiona
 Radiant Research - Portland
 5331 SW Macadam Ave
 Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
 Medical Director
 Covance CRU, Inc.
 3402 Kinsman Boulevard
 Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
 Significant/ Adverse
 Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	61		31-106 U/L
ALT (SGPT)	45	H	6-34 U/L
AST (SGOT)	26		9-34 U/L
GGT	42		4-49 U/L
LDH	156		53-234 U/L
Urea Nitr	21		4-24 mg/dL
Creatinine	1.2	H	0.4-1.1 mg/dL
Glucose	103		70-115 mg/dL
Uric Acid	7.4	H	2.1-7.2 mg/dL
Calcium	10.2		8.3-10.6 mg/dL
Phosphorus	3.9		2.2-5.1 mg/dL
Total Prot	7.0		6.1-8.4 g/dL
Albumin	4.5		3.3-4.9 g/dL
Sodium	143		132-147 mEq/L
Potassium	4.4		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L

[]

[X]

[]

[X]

[]

[X]

Investigator Signature:

Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
 T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

J14315

(INV)

Covance CLS

Marietta Henry, M.D., Director
8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N574619

Page 2 of 3

INVESTIGATOR: (J14315)

Keith Klatt, M.D.
c/o Heather Aiona
Radiant Research - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	17.5	H	11.6-16.4 g/dL	[]	[X]
HCT	50	H	34-48 %	[]	[X]
RBC	5.4		4.1-5.6x10 ⁶ /uL		
MCV	92		79-98 fL		
MCH	32		26-34 pg		
MCHC	35		31-38 g/dL		
RDW	12.5		12.0-15.0 %		
RBC Morph	Normocytic				
WBC	6.36		3.80-10.70 x10 ³ /uL		
Neutrophil	4.00		1.96-7.23 x10 ³ /uL		
Lymphocyte	1.86		0.91-4.28 x10 ³ /uL		
Monocytes	0.28		0.12-0.92 x10 ³ /uL		
Eosinophil	0.20		0.00-0.57 x10 ³ /uL		
Basophils	0.03		0.00-0.20 x10 ³ /uL		
Neutrophil	62.9		40.5-75.0 %		
Lymphocyte	29.3		15.4-48.5%		
Monocytes	4.4		2.6-10.1 %		
Eosinophil	3.1		0.0-6.8 %		
Basophils	0.4		0.0-2.0 %		
Platelets	166		140-400 x10 ³ /uL		

Investigator Signature:

Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

J14315

(INV)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

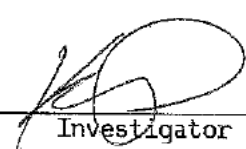
Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.009	1.003-1.035
pH	5.0	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Negative	


Investigator Signature:


Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 107 30-160 ug/dL

FOLLICLE STIMULATING HORMONE

FSH 6.0

Follicular:

4.0-13.0 mIU/mL

Mid-Cycle:

5.0-22.0 mIU/mL

Luteal:

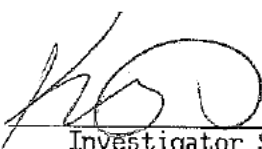
2.0-13.0 mIU/mL

Postmenopausal:

20.0-138.0 mIU/mL

HEPATITIS A ANTIBODY-IGM

HepA IgMab Negative No Ref Rng


Investigator Signature:


Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
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Madison, WI United States 53704

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B SURFACE ANTIGEN

HBsAg Negative No Ref Rng

HEPATITIS C VIRUS ANTIBODY

ANTI-HCV Negative No Ref Rng

HEPATITIS B SURFACE ANTIBODY

HBsAb Negative No Ref Rng

ESTRADIOL - See Note #1

Note #1 - No specimen received

Investigator Signature:

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INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

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DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive

Investigator Signature:

5/4309
Date:

"This testing is performed as part of a clinical trial. Diagnostic testing shall be conducted locally." H(High) or L(Low)=Values above or below Covance reference range T=Telephoned P="Panic" EX=Exclusions as specified by the Sponsor

J14315

(INV)

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Medical Director
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3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 10:34 DATE: 02-Feb-2007

DATE RECEIVED IN LABORATORY: 03-Feb-2007

DATE REPORTED BY LABORATORY: 03-Feb-2007

SEX: F BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

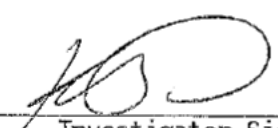
Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative

Ref Rng: Negative


Investigator Signature:

5 Feb 2007
Date:

H(High) or L(Low): Values above or below Covance CLS reference range
T-Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

J14315

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PROTOCOL 6270-229
INVESTIGATOR NO.: 4
RANDOMIZATION NUMBER:
PATIENT INITIALS: (b) (6)
VISIT: 1

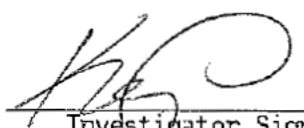
Screen
COLLECTION TIME: 10:34 DATE: 02-Feb-2007
DATE RECEIVED IN LABORATORY: 03-Feb-2007
DATE REPORTED BY LABORATORY: 03-Feb-2007
SEX: F BIRTHDATE: (b) (6) AGE: 31
SCREENING NUMBER: 54019

Is this Clinically
Significant/ Adverse
Event?

Yes No

HAS PATIENT FASTED 8 HOURS?
Fasted? Yes

IS SUBJECT A SMOKER OR NON-SM?
smoker/non Smoker


Investigator Signature:

5F4307
Date:

J14315

(INV)

Covance CLS

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N970629

Page 1 of 1

INVESTIGATOR: (J14315)

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5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 21-Jan-2008

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

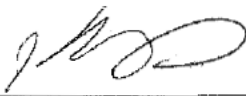
No

OXIDIZED LDL

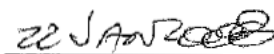
OxidizeLDL

102

30-110 U/L



Investigator Signature:



Date:

H(High) or L(Low)-Values above or below reference range.
Testing performed by: Pacific Biometrics
220 West Harrison Street, Seattle, WA 98119

J14315

(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N970629

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Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 19-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

FIBRINOGEN - See Note #1

Fibrinogen Awaiting specimen arrival

Note #1 - Specimen not submitted; please ship or testing will be canceled.

Investigator Signature:

26 Feb 2007
Date:

H(K) or L(L)-Values above or below Covance CLS reference range
T-Telephoned P-"Panic" EX-Exclusion-as specified by the sponsor

J14315

(INV)

Covance CLS

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 19-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?


Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 50

mg/dL No Ref Rng


Investigator Signature:


Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 23-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1

sICAM-1

297

115-306 ng/mL

Investigator Signature:

27 Feb 2007
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
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PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 19-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1 - See Note #1

sICAM-1 Awaiting specimen arrival

Note #1 - Specimen not submitted; please ship or testing will be canceled.

Investigator Signature:

26 Feb 2007
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
I-Telephoned P="Panic" EX-Exclusion-as specified by the sponsor

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

No

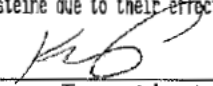
HOMOCYSTEINE

*1 HCY

8.25

5.90-16.00 umol/L

Note #1 - WARNING: Specimens from patients who are on drug therapy involving S-adenosyl-methionine may show falsely elevated levels of homocysteine. Specimens from patients taking methotrexate, carbamazepine, phenytoin, nitrous oxide or 6-azauridine triacetate may have elevated levels of homocysteine due to their effect on the metabolic pathway.


Investigator Signature:

23 Apr 2007
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 19-Feb-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

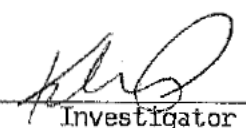
Is this Clinically
Significant/ Adverse
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed


Investigator Signature:


Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

DATE RECEIVED IN LABORATORY: 19-Feb-2007

DATE REPORTED BY LABORATORY: 12-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

Yes

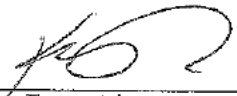
No

HOMOCYSTEINE

Homocys

8.25

5.90-16.00 umol/L


Investigator Signature:

19 MAR 2007
Date:

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LABORATORY REPORT

ACCESSION NO. N970629

Page 1 of 1

INVESTIGATOR: (J14315)

Keith Klatt, M.D.
c/o Heather Aiona
Radiant Research - Portland
5331 SW Macadam Ave
Portland, OR 97239

SPONSOR REPORT TO:

Russell M. Dixon, MD
Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 4

RANDOMIZATION NUMBER: R4003

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 07:30 DATE: 17-Feb-2007

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SEX: M BIRTHDATE: (b) (6) AGE: 31

SCREENING NUMBER: S4019

Is this Clinically
Significant/ Adverse
Event?

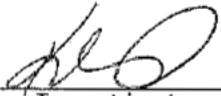
Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes


Investigator Signature:

26 Feb 07
Date:

J14315

(INV)

Covance CLS

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Yes

No

HEMOGLOBIN A1C

Hgb A1c


5.0

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%


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No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

Note #1 - Specimen not submitted; please ship or testing will be canceled.

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Testing performed by: Pacific Biometrics
220 West Harrison Street; Seattle, WA 98119

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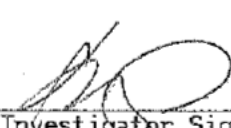
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Yes

No

FIBRINOGEN

Fibrinogen 307 200-400 mg/dL


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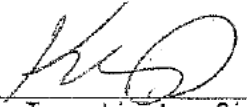
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Yes No

LIPID PANEL

Triglycer	127	39-176 mg/dL
Cholest	200	141-240 mg/dL
HDL Dex-S	42	28-63 mg/dL
LDL Chol	133	78-185 mg/dL


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Yes

No

CHEMISTRY PANEL

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	56		31-106 U/L
ALT (SGPT)	43	H	6-34 U/L
AST (SGOT)	22		9-34 U/L
GGT	30		4-49 U/L
LDH	170		53-234 U/L
Urea Nitr	18		4-24 mg/dL
Creatinine	1.2	H	0.4-1.1 mg/dL
Glucose	99		70-115 mg/dL
Uric Acid	7.0		2.1-7.2 mg/dL
Calcium	9.8		8.3-10.6 mg/dL
Phosphorus	3.7		2.2-5.1 mg/dL
Total Prot	6.9		6.1-8.4 g/dL
Albumin	4.4		3.3-4.9 g/dL
Sodium	146		132-147 mEq/L
Potassium	4.0		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L

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Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	16.9	H	11.6-16.4 g/dL
HCT	50	H	34-48 %
RBC	5.3		4.1-5.6x10 ⁶ /uL
MCV	96		79-98 fL
MCH	32		26-34 pg
MCHC	34		31-38 g/dL
RDW	13.2		12.0-15.0 %
RBC Morph	Normocytic		
WBC	7.33		3.80-10.70 x10 ³ /uL
Neutrophil	4.56		1.96-7.23 x10 ³ /uL
Lymphocyte	2.23		0.91-4.28 x10 ³ /uL
Monocytes	0.29		0.12-0.92 x10 ³ /uL
Eosinophil	0.20		0.00-0.57 x10 ³ /uL
Basophils	0.05		0.00-0.20 x10 ³ /uL
Neutrophil	62.2		40.5-75.0 %
Lymphocyte	30.5		15.4-48.5%
Monocytes	3.9		2.6-10.1 %
Eosinophil	2.7		0.0-6.8 %
Basophils	0.6		0.0-2.0 %
Platelets	138	L	140-400 x10 ³ /uL

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Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.011	1.003-1.035
pH	6.0	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Negative	

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Yes No

TOTAL IRON

Total Iron 86 30-160 ug/dL

C-REACTIVE PROTEIN

CRP-HS 0.187 <=0.287 mg/dL

CARBOXYHEMOGLOBIN

Carboxyhem 5.8 % saturation
No Ref Rng

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