

CRF Report for Study E6270229

Report run by Jaedeanne Shaver at 11-01-2008 10:57:09

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 2015

Ending patient: 2015

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	Abc 123

All time stamps displayed in this report are in the timezone of the database server.

The data contained in this report is current at the time of printing (time as shown above)

Page ID: D11656313

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Dallas
Investigator: Patricia Chandler
Date: 07-MAR-2008

Patient#: 2015
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Weight & Height WEEK 0 (BASELINE) Disc ID: 1346156213 Type: MANUAL	5 17MAY07 Closed: N	Please verify the weights to be reported for the W0 & W24 assessments.	<input checked="" type="checkbox"/> W0=087.0 kg W24=131.0 kg <input type="checkbox"/> W0=_____ kg W24=_____ kg

Dm2
07/13/08

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

11 MAR 2008

Date

Data Clarification Form

To: Covance CRU Dallas
Investigator: Patricia Chandler
Date: 01-MAR-2008

Patient#: 2015
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Laboratory Evaluation SCREENING Disc ID: 1324724413 Type: MANUAL HEADER	23APR07 Closed: N	The following lab req/documentation was not provided with this crf. Please forward with this dcf: Screening Req #O021460 W0 Urine collection Req # O621407 Unscheduled Req #O410268	Req #O021460 <input checked="" type="checkbox"/> Attached [] Other: _____ Req # O621407 <input checked="" type="checkbox"/> Attached [] Other: _____ Req #O410268 <input checked="" type="checkbox"/> Attached [] Other: _____
Unused Study Product Returned WEEK 1 Disc ID: 1324724313 Type: MANUAL	8 24MAY07 Closed: N	Original, Spice and Frost flavors were dispensed at W0, however product returned at W1 provides for Original and Spice only.	[] W0 Dispensation: Original = 1 Spice = 1 <input checked="" type="checkbox"/> W1 Returned: Original = 00 Spice = 00 Frost = 00

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

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. 0021460

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.
c/o Mark Schambura
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

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.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 09:15 DATE: 23-Apr-2007

DATE RECEIVED IN LABORATORY: 24-Apr-2007

DATE REPORTED BY LABORATORY: 24-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

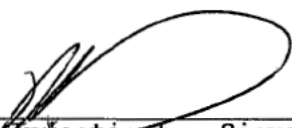
IS SUBJECT A SMOKER OR NON-SM?

smoker/non

Smoker

QC'D

8/17 MAY 2007


Investigator Signature:
Date:

B18097

(INV)

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ALERT FAX REPORT

Sponsor : R J Reynolds Tobacco Co. Investigator Name: Patricia Chandler, M.D.
Protocol : 6270-229 Investigator ID : 2

Patient ID : S2095 Alert Recipient : Mark Schambura
Patient Initials : (b) Alert Fax Number : 1-214-920-9057
Patient Sex : F
Patient DOB : (b) (6)

Visit Description: Screen Collection Date : 23-APR-2007
Accession Number : 0021460 Collection Time : 09:15

HEPATITIS B SURFACE ANTIBODY

Test Name	Result	Reference Range	Flags
HBSAB	Positive	No Ref Rng	EX

Flag Key(s)
EX

Exclusion

QCD

Handwritten: 26 APR 2007

Covance CLS

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LABORATORY REPORT

ACCESSION NO. 0021460

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 09:15 DATE: 23-Apr-2007

DATE RECEIVED IN LABORATORY: 24-Apr-2007

DATE REPORTED BY LABORATORY: 24-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

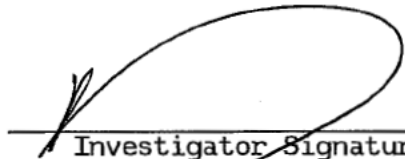
No

SCREEN CHEMISTRY PANEL

Total Bili	0.4		0.2-1.2 mg/dL
Alk Phos	114	H	31-106 U/L
ALT (SGPT)	9		6-34 U/L
AST (SGOT)	15		9-34 U/L
GGT	46		4-49 U/L
LDH	178		53-234 U/L
Urea Nitr	11		4-24 mg/dL
Creatinine	0.8		0.4-1.1 mg/dL
Glucose	95		70-115 mg/dL
Uric Acid	3.2		2.1-7.2 mg/dL
Calcium	10.3		8.3-10.6 mg/dL
Phosphorus	3.6		2.2-5.1 mg/dL
Total Prot	7.9		6.1-8.4 g/dL
Albumin	4.7		3.3-4.9 g/dL
Sodium	143		132-147 mEq/L
Potassium	4.3		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L
Triglycer	84		45-214 mg/dL
Cholest	247		155-265 mg/dL

OCD

23 MAY 2007


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

B18097

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INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 09:15 DATE: 23-Apr-2007

DATE RECEIVED IN LABORATORY: 24-Apr-2007

DATE REPORTED BY LABORATORY: 24-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	12.9		11.6-16.4 g/dL
HCT	39		34-48 %
RBC	4.5		4.1-5.6x10 ⁶ /uL
MCV	85		79-98 fL
MCH	29		26-34 pg
MCHC	33		31-38 g/dL
RDW	14.7		12.0-15.0 %
RBC Morph	Normocytic		
WBC	13.99	H	3.80-10.70 x10 ³ /uL
Neutrophil	10.58	H	1.96-7.23 x10 ³ /uL
Lymphocyte	2.82		0.91-4.28 x10 ³ /uL
Monocytes	0.45		0.12-0.92 x10 ³ /uL
Eosinophil	0.08		0.00-0.57 x10 ³ /uL
Basophils	0.05		0.00-0.20 x10 ³ /uL
Neutrophil	75.6	H	40.5-75.0 %
Lymphocyte	20.2		15.4-48.5 %
Monocytes	3.3		2.6-10.1 %
Eosinophil	0.5		0.0-6.8 %
Basophils	0.4		0.0-2.0 %
Platelets	285		140-400 x10 ³ /uL

QC'D

Investigator Signature:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

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Screen

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SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

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	1.013	1.003-1.035
pH	5.5	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	Positive	

MISCELLANEOUS ELEMENTS

Mucous	Present	Ref Rng: Not present
--------	---------	----------------------

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 09:15 DATE: 23-Apr-2007

DATE RECEIVED IN LABORATORY: 24-Apr-2007

DATE REPORTED BY LABORATORY: 24-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 40 30-160 ug/dL

FOLLICLE STIMULATING HORMONE

FSH 54.5

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:
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INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 09:15 DATE: 23-Apr-2007

DATE RECEIVED IN LABORATORY: 24-Apr-2007

DATE REPORTED BY LABORATORY: 25-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

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
#1 HBSAB EX Positive

No Ref Rng

[]

[]

ESTRADIOL
Estradiol <1.4

pg/mL
See Inv. Manual

Note #1 - Result verified by repeat analysis

Investigator Signature:

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: (b) (6)

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 09:15 DATE: 23-Apr-2007

DATE RECEIVED IN LABORATORY: 24-Apr-2007

DATE REPORTED BY LABORATORY: 24-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2


Non-Reactive

Reference Range:

Non-Reactive

QC'D

8/17 MAY 2007


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

B18097

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ACCESSION NO. 0021460

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 09:15 DATE: 23-Apr-2007

DATE RECEIVED IN LABORATORY: 24-Apr-2007

DATE REPORTED BY LABORATORY: 24-Apr-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

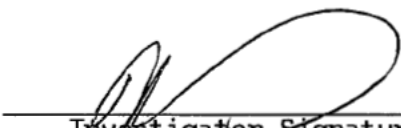
No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng: Negative

QCD

28 MAY 2007


Investigator Signature:
Date:

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B18097

(INV)

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LABORATORY REPORT

ACCESSION NO. 0621407

Page 1 of 1

INVESTIGATOR: (B18097)

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection 14:29

COLLECTION TIME: 15:45 DATE: 17-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 21-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1354

UAlq24Crea 80.2

600-1600 mg/24hr

mg/dL No Ref Rng

ELAPSED DATE AND TIME, 24HR

Elpsd D&T 1440

min

24 HR COLLECTION INFORMATION

Start Date 17-May-2007

Start Time ① 15:45 16:05

Stop Date 18-May-2007

Stop Time ① 15:45 14:29

TOTAL 24HR URINE VOLUME

Total Vol. 1688

mL

QCD

28188SEP2007
Investigator Signature:
Date:

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B18097

(INV)

① correction
SF 6/10/2008

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LABORATORY REPORT

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:45 DATE: 17-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 05-Apr-2008

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1450

UAlq24Crea 80.2

600-1600 mg/24hr

mg/dL No Ref Rng



Investigator Signature:

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

30 Apr 2008
Date:

B18097

(INV)

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LABORATORY REPORT

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:45 DATE: 17-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 04-Apr-2008

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

24 HR COLLECTION INFORMATION

Start Date 17-May-2007
Start Time 16:05
Stop Date 18-May-2007
Stop Time 14:29

Investigator Signature:

Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:45 DATE: 17-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 03-Apr-2008

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

ELAPSED DATE AND TIME, 24HR

Elpsd D&T

1344

min

Investigator Signature:

Date:

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LABORATORY REPORT

**** REPRINTED: 16-MAY-2007 ****

ACCESSION NO. 0410268

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Retest

COLLECTION TIME: 16:47 DATE: 03-May-2007

DATE RECEIVED IN LABORATORY: 04-May-2007

DATE REPORTED BY LABORATORY: 04-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	11.8	11.6-16.4 g/dL
HCT	35	34-48 %
RBC	4.3	4.1-5.6x10 ⁶ /uL
MCV	81	79-98 fL
MCH	27	26-34 pg
MCHC	34	31-38 g/dL
RDW	14.8	12.0-15.0 %
RBC Morph	Normocytic	
WBC	9.86	3.80-10.70 x10 ³ /uL
Neutrophil	6.39	1.96-7.23 x10 ³ /uL
Lymphocyte	2.79	0.91-4.28 x10 ³ /uL
Monocytes	0.48	0.12-0.92 x10 ³ /uL
Eosinophil	0.18	0.00-0.57 x10 ³ /uL
Basophils	0.03	0.00-0.20 x10 ³ /uL
Neutrophil	64.7	40.5-75.0 %
Lymphocyte	28.3	15.4-48.5 %
Monocytes	4.9	2.6-10.1 %
Eosinophil	1.8	0.0-6.8 %
Basophils	0.3	0.0-2.0 %
Platelets	298	140-400 x10 ³ /uL

QC'D

8 MAY 2007

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

B18097

(INV)

CRF Report for Study E6270229



Patient: 2015

CRF: Header_Page

Visit: SCREENING

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 23-04-2007

Entry Time: 06-07-2007 10:43:17

Modification Time: 12-07-2007 18:57:17

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 1

Document #: R147691513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Header_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 23-04-2007

Entered By: Sharon Ladenes

Entry Time: 06-07-2007 10:43:17

Last Modification Time: 12-07-2007 18:57:17

Page number: 1

RDC CASE REPORT FORM

SMOKER

Sponsor Name

Investigator

Site

RJ REYNOLDS TOBACCO COMPANY

PATRICIA A. CHANDLER, MD

DALLAS 002

SWITCHING FROM USUAL BRAND CIGARETTES TO A TOBACCO-HEATING CIGARETTE OR SNUS

-A MULTI-CENTER EVALUATION OF HEALTH-RELATED QUALITY OF LIFE ASSESSMENTS AND BIOMARKERS

OF EXPOSURE AND HARM

CRF Report for Study E6270229

Patient: 2015

CRF: Screening

Visit: SCREENING

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 23-04-2007

Entry Time: 06-07-2007 10:44:27

Modification Time: 06-01-2008 16:57:16

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 2

Document #: R147691913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:44:27	
		Last Modification Time: 17-09-2007 17:40:19	
		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: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:44:27	
		Last Modification Time: 06-07-2007 10:52:16	
		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: 2015

CRF: Screening

Visit: SCREENING

Site: CD_001

Blank? N

Visit Date: 23-04-2007

Investigator: RR_001

CRF Page #: 2

Document #: R147691913

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).	YES
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: 23-04-2007	Entry Time: 06-07-2007 10:44:27	
Entered By: Sharon Ladenes		Last Modification Time: 06-07-2007 10:52:16	Page number: 3	
Exclusion Criteria				Yes/No
Sequence number				
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

CRF Report for Study E6270229



Patient: 2015
CRF: Screening
Visit: SCREENING

Site: CD_001
Blank? N
Visit Date: 23-04-2007

Investigator: RR_001
CRF Page #: 2
Document #: R147691913

Section: Informed_Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:44:27	
		Last Modification Time: 06-07-2007 10:52:16	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form		23-04-2007	

Section: Elig	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:44:27	
		Last Modification Time: 06-07-2007 10:52:16	
		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	Criteria		
Type	Number	Deviation	Date Exemption Granted

Section: Patient_Rep_Outc	6 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:44:27	
		Last Modification Time: 06-07-2007 10:52:16	
		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: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:44:27	
		Last Modification Time: 06-07-2007 10:52:16	
		Page number: 5	
Demographics		Subject Initials	
Date of Birth	Gender	Height	Height Unit
(b) (6)	F	169.1	CM
		xxx.x	
		Weight	Weight Unit
		084.8	KG
		xxx.x	
Ethnicity			

CRF Report for Study E6270229

Patient: 2015

CRF: Screening

Visit: SCREENING

Site: CD_001

Blank? N

Visit Date: 23-04-2007

Investigator: RR_001

CRF Page #: 2

Document #: R147691913

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

Section: Vital		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 23-04-2007		Entry Time: 06-07-2007 10:44:27			
Entered By: Sharon Ladenes		Last Modification Time: 06-07-2007 10:52:16		Page number: 5			
VITAL SIGNS							
Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit	
0837	Systolic	Diastolic	064	16	036.2	C	
	114	070			xxx.x		
Comments							

Section: Hdyf_Oral_Health		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 23-04-2007		Entry Time: 06-07-2007 10:44:27			
Entered By: Sharon Ladenes		Last Modification Time: 06-07-2007 10:52:16		Page number: 5			
HDYF? / ORAL HEALTH QUESTIONS INQUIRY							
Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments				
NR	YES	YES					

Section: Lab_Eval		10 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 23-04-2007		Entry Time: 06-07-2007 10:44:27			
Entered By: Sharon Ladenes		Last Modification Time: 06-01-2008 16:57:16		Page number: 6			
Laboratory Evaluations							
Were the scheduled laboratory samples obtained?				YES		No, specify	
Requisition Number 1		O021460					
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: 2015

CRF: Screening2

Visit: SCREENING

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 23-04-2007

Entry Time: 06-07-2007 10:52:17

Modification Time: 06-12-2007 17:21:33

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 3

Document #: R147694813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:52:17	
		Last Modification Time: 06-07-2007 10:56:44	
		Page number: 6	
Urine Pregnancy Test			
Result			
NEGA			
TIVE			

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:52:17	
		Last Modification Time: 06-07-2007 10:56:44	
		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: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:52:17	
		Last Modification Time: 06-07-2007 10:56:44	
		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: 23-04-2007	
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:52:17	
		Last Modification Time: 06-07-2007 10:56:44	
		Page number: 7	

CRF Report for Study E6270229

Patient: 2015

CRF: Screening2

Visit: SCREENING

Site: CD_001

Blank? N

Visit Date: 23-04-2007

Investigator: RR_001

CRF Page #: 3

Document #: R147694813

Section: Med_Hx

4 of 10

Medical History

Does the subject have any relevant medical history?

YES

If so, list the specific diagnosis and/or procedure.

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT			
BREASTS			
RESP			
CARDIO			
LYMPH/HEMA			
GASTRO			
GENITO	HYSTERECTOMY	06-05-2003	06-05-2003
MUSCULO			
ENDOCRINE			
NEURO			
IMMUNO			
PSYCH			
ALLERGIC			
OTHER			

Section: ECG

5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 23-04-2007

Entered By: Sharon Ladenes

Entry Time: 06-07-2007 10:52:17

Last Modification Time: 06-07-2007 10:56:44

Page number: 8

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

0843

067

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

160

084

400

422

ECG INTERPRETATION:

ANCS

Comments (related to abnormal, CS findings only):

Section: Usual_Brand_Cig

6 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 23-04-2007

Entered By: Sharon Ladenes

Entry Time: 06-07-2007 10:52:17

Last Modification Time: 18-09-2007 14:30:30

CRF Report for Study E6270229

Patient: 2015
CRF: Screening2
Visit: SCREENING

Site: CD_001
Blank? N
Visit Date: 23-04-2007

Investigator: RR_001
CRF Page #: 3
Document #: R147694813

Section: Usual_Brand_Cig		6 of 10		Page number: 9	
USUAL BRAND CIGARETTE PACK DATA					
Usual Brand	Type	Length			
NEWPORT	MENTHOL	LONG 90-105MM			
How long have these been the subject's usual brand?					
Style	Pack	00	months		
REGULAR	HARD	01	years		

Section: Ftc_Tar_Level		7 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 23-04-2007					
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:52:17					
		Last Modification Time: 18-09-2007 14:26:22					
		Page number: 9					
FTC TAR LEVEL OF USUAL BRAND							
FTC Tar Level (mg)							
19.9							

Section: Expired_Carbon_M		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 23-04-2007					
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:52:17					
		Last Modification Time: 06-07-2007 10:57:16					
		Page number: 10					
EXPIRED CARBON MONOXIDE							
Actual Time	ECO Level (ppm)	%COHb	Comments				
0900	10	02.2					

Section: Best_Baseline_Sp		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 23-04-2007					
Entered By: Sharon Ladenes		Entry Time: 06-07-2007 10:52:17					
		Last Modification Time: 06-12-2007 17:21:33					
		Page number: 10					
BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time	FEV1 Predicted	FVC Predicted					
of FEV1/FVC Test	(%)	(%)					
0903	111	111					
Testing Position	FEV1 L	FVC L					
STANDING	3.08	3.73					
Comments							

Irvs Training		10 10		N		Entry Complete	
---------------	--	-------	--	---	--	----------------	--

CRF Report for Study E6270229

Patient: 2015

CRF: Screening2

Visit: SCREENING

Site: CD_001

Blank? N

Visit Date: 23-04-2007

Investigator: RR_001

CRF Page #: 3

Document #: R147694813

Section: Irvs_Training	10 of 10	Blank?	Section Date: 23-04-2007	Section Status:
Visit: SCREENING			Entry Time: 06-07-2007 10:52:17	
Entered By: Sharon Ladenes			Last Modification Time: 06-07-2007 10:58:26	
		Page number: 10		
IVRS TRAINING				
Did Subject receive training on the Daily Call-In Diary (IVRS)?				
YES				

CRF Report for Study E6270229



Patient: 2015

CRF: Week-2

Visit: WEEK -2

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 03-05-2007

Entry Time: 18-09-2007 14:27:09

Modification Time: 18-09-2007 14:27:39

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 4

Document #: R157118913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Usual_Brand_Coll

Blank? N

Section Status: Entry Complete

Visit: WEEK -2

Section Date: 03-05-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:27:09

Last Modification Time: 18-09-2007 14:27:39

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

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 17-05-2007

Entry Time: 13-08-2007 19:54:53

Modification Time: 09-01-2008 18:13:11

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 5

Document #: R152554213

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 13-08-2007 19:58:36	
		Page number: 12A	

Date	PRO QUESTIONNAIRES	YES / NO
17-05-2007	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 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 13-08-2007 19:58:36	
		Page number: 12A	

Date	Drug Screen
17-05-2007	Drug Screen Result NEG

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 13-08-2007 19:58:36	
		Page number: 12A	

Date	Alcohol Screen
17-05-2007	Breathalyzer Result NEG

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 13-08-2007 19:58:36	
		Page number: 12A	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 17-05-2007

Investigator: RR_001

CRF Page #: 5

Document #: R152554213

Section: Preg_Test	4 of 11
Pregnancy Test	
Date	Result
17-05-2007	NEGA TIVE

Section: Urine_Coll	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 05-12-2007 22:05:18	
		Page number: 12A	

24-Hour Urine Collection						
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	17-05-2007	1605	NA	NA	NA	
0 HOUR TO 24 HOURS	17-05-2007	1605	18-05-2007	1429	1688	

Section: Hdyf_Oral_Health	6 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 09-01-2008 18:13:11	
		Page number: 13.1	
HDYF? INQUIRY			
Date	Actual Time	HDYF Performed?	Comments
18-05-2007	1000	YES	

Section: Vital	7 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 13-08-2007 19:58:36	
		Page number: 13.1	
VITAL SIGNS			
		Blood Pressure	Oral
Date	Actual Time	Systolic	Diastolic
17-05-2007	1555	105	069
		Pulse	Respiratory Rate
		088	16
			Temperature
			037.0
			xxx.x
Unit			C
Comments			

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 17-05-2007

Investigator: RR_001

CRF Page #: 5

Document #: R152554213

Section: Oral_Health_Exam	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 01-11-2007 20:02:34	
		Page number: 13.1	

ORAL HEALTH EXAMINATION			
Date	Procedure	Relevant Findings?*	Findings
17-05-2007	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: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 13-08-2007 19:58:36	
		Page number: 14.1	

PHYSICAL EXAMINATION				
Date	Code Number	Code	Relevant Findings?	Findings
17-05-2007	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	NE	

Section: Weight_Height	10 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 17-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:54:53	
		Last Modification Time: 13-08-2007 19:58:36	
		Page number: 14.1	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 17-05-2007

Investigator: RR_001

CRF Page #: 5

Document #: R152554213

Section: Weight_Height 10 of 11

WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
17-05-2007	087.0	KG	ND	CM
	xxx.x		xxx.x	

Section: Lab_Eval 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 17-05-2007

Entered By: Sharon Ladenes

Entry Time: 13-08-2007 19:54:53

Last Modification Time: 18-09-2007 14:32:35

Page number: 15.1

Laboratory Evaluations

Date

18-05-2007

Were the scheduled laboratory samples obtained?

YES

No, specify

Requisition Number 1

N526978

Requisition Number 2 (if applicable)

O621407

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: 2015

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 18-05-2007

Entry Time: 13-08-2007 19:58:37

Modification Time: 09-01-2008 18:13:38

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 5.1

Document #: R152554313

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: 18-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:58:37	
		Last Modification Time: 13-08-2007 20:06:09	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
18-05-2007	0612		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:58:37	
		Last Modification Time: 13-08-2007 20:06:09	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
18-05-2007	1440	12	02.5

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:58:37	
		Last Modification Time: 13-08-2007 20:06:09	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
18-05-2007	1446		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:58:37	
		Last Modification Time: 08-01-2008 18:01:54	
		Page number: 16.1	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 18-05-2007

Investigator: RR_001

CRF Page #: 5.1

Document #: R152554313

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time							
of FEV1/FVC		Testing				FVC	
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
18-05-2007	1510	STANDI	2.79	100	3.24	107	
		NG					

Section: Proventil_Admin	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:58:37	
		Last Modification Time: 13-08-2007 20:06:09	
		Page number: 16.1	
PROVENTIL ADMINISTRATION			
	Actual Time of Proventil		
Date	Administration	Amount Administered	Comments
18-05-2007	1540	2 METERED PUFFS	

Section: Post_Bronch_Spir	6 of 11	Blank? N	Section Status: Entry Complete				
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007					
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:58:37					
		Last Modification Time: 09-01-2008 18:13:38					
		Page number: 16.1					
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
	Actual Time of FEV1/FVC	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						
18-05-2007	1556	STANDING	2.79	101	3.61	107	

Section: Unused_Usual_Bra	7 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007	
Entered By: Sharon Ladenes		Entry Time: 13-08-2007 19:58:37	
		Last Modification Time: 13-08-2007 20:06:09	
		Page number: 17.1	
Unused Usual Brand Cigarette Pack Collection			
			Yes / No
Date	Does Site have 5 unopened packs of subject's usual brand cigarette to ship to CCLS?		YES
17-05-2007			

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 18-05-2007

Investigator: RR_001

CRF Page #: 5.1

Document #: R152554313

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007		Entry Time: 13-08-2007 19:58:37			
Entered By: Sharon Ladenes		Last Modification Time: 13-08-2007 20:06:09		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	16-05- 2007	0700	17-05-2007	0700	12	NO		
24 HOURS IN-HOUSE	17-05- 2007	1430	18-05-2007	1430	6	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007		Entry Time: 13-08-2007 19:58:37			
Entered By: Sharon Ladenes		Last Modification Time: 08-01-2008 18:02:31		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT			Cigarette Butt Number	Cigarette Butt Measurement (mm)
Date	Scheduled Collection Period			
17-05-2007	24 HOURS PRIOR TO CHECK-IN		1	45
			2	50
			3	48
			4	49
			5	59
			6	45
			7	38
			8	33
			9	51
			10	46
			11	39
			12	37

Section: Used_Butt_Measur		10 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 18-05-2007		Entry Time: 13-08-2007 19:58:37			
Entered By: Sharon Ladenes		Last Modification Time: 08-01-2008 18:04:16					

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CD_001

Blank? N

Visit Date: 18-05-2007

Investigator: RR_001

CRF Page #: 5.1

Document #: R152554313

Section: Used_Butt_Measur 10 of 11

Last Modification Time:

Page number: 19.1

USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date
18-05-2007

Period
24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1

52

2

51

3

51

4

41

5

50

6

52

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 18-05-2007

Entered By: Sharon Ladenes

Entry Time: 13-08-2007 19:58:37

Last Modification Time: 13-08-2007 20:06:09

Page number: 20.1

RANDOMIZATION

Date
18-05-2007

Actual Time
1627

Randomization Sequence
GROUP B

CRF Report for Study E6270229

Patient: 2015

CRF: Week 0 3baseline

Visit: WEEK 0 (BASELINE)

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 18-05-2007

Entry Time: 13-08-2007 20:06:10

Modification Time: 08-01-2008 18:30:49

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 5.2

Document #: R152554413

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Prod_Dispe

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 18-05-2007

Entered By: Sharon Ladenes

Entry Time: 13-08-2007 20:06:10

Last Modification Time: 08-01-2008 18:30:49

Page number: 23.1

STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
18-05-2007	1700	SNUS	SPICE	1
18-05-2007	1700	SNUS	ORIGINAL	1
18-05-2007	1700	SNUS	FROST	1

CRF Report for Study E6270229

Patient: 2015

CRF: Intercurrent_III

Visit: INTERCURRENT ILL

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 25-05-2007

Entry Time: 11-12-2007 12:20:23

Modification Time: 11-12-2007 12:20:33

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 7

Document #: R169421113

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 25-05-2007

Entered By: Sharon Ladenes

Entry Time: 11-12-2007 12:20:23

Last Modification Time: 11-12-2007 12:20:33

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
----------	-----------------	------	---------------	----------------------------	------	----------	------------------------------	--------------

CRF Report for Study E6270229

Patient: 2015

CRF: Week 1

Visit: WEEK 1

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment: Source documents lost

Site: CD_001

Blank? N

Visit Date: 24-05-2007

Entry Time: 10-10-2007 21:18:12

Modification Time: 09-01-2008 18:14:59

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 8

Document #: R161217013

CRF Status: Entry Complete

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 24-05-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:18:12	
		Last Modification Time: 08-01-2008 18:40:58	
		Page number: 22	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions Performed?	
Actual Time	HDYF Performed?	Comments	
UNK	UNK	SOURCE DOCUMENTS LOST	

Section: Vital	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 24-05-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:18:12	
		Last Modification Time: 08-01-2008 18:41:33	
		Page number: 22	
VITAL SIGNS			
	Blood Pressure	Oral Temperature	Unit
Actual Time	Systolic Diastolic	Pulse Respiratory Rate	
UNK	UNK UNK	UNK UNK	C
		xxx.x	
Comments			

Section: Expired_Carbon_M	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 24-05-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:18:12	
		Last Modification Time: 08-01-2008 18:42:11	
		Page number: 22	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
UNK	UNK	UNK	

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

Patient: 2015
CRF: Week 1
Visit: WEEK 1

Site: CD_001
Blank? N
Visit Date: 24-05-2007

Investigator: RR_001
CRF Page #: 8
Document #: R161217013

Section: Unused_Study_Pro 4 of 5

Visit: WEEK 1

Entered By: Sharon Ladenes

Section Date: 24-05-2007

Entry Time: 10-10-2007 21:18:12

Last Modification Time: 11-12-2007 12:20:08

Page number: 23

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches
SNUS	ORIGINAL	00	00
SNUS	SPICE	00	00

Section: Study_Prod_Dispe 5 of 5

Visit: WEEK 1

Entered By: Sharon Ladenes

Blank? N

Section Date: 24-05-2007

Entry Time: 10-10-2007 21:18:12

Last Modification Time: 09-01-2008 18:14:59

Page number: 23

Section Status: Entry Complete

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
NR	SNUS	ORIGINAL	0
NR	SNUS	FROST	0
NR	SNUS	SPICE	0

CRF Report for Study E6270229

Patient: 2015

CRF: Week 2

Visit: WEEK 2

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 01-06-2007

Entry Time: 10-10-2007 21:21:40

Modification Time: 08-01-2008 18:43:30

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 9

Document #: R161217513

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 01-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:21:40	
		Last Modification Time:	
		Page number: 24	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health	
		Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 01-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:21:40	
		Last Modification Time:	
		Page number: 24	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Comments			

Section: Expired_Carbon_M	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 01-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:21:40	
		Last Modification Time:	
		Page number: 24	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Blood_Sampl_Cohb	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2		Section Date: 01-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:21:40	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2015
CRF: Week 2
Visit: WEEK 2

Site: CD_001
Blank? Y
Visit Date: 01-06-2007

Investigator: RR_001
CRF Page #: 9
Document #: R161217513

Section: Blood_Sampl_Cohb	4 of 6	Page number: 24
Blood Sampling for %COHb		
Actual Time	Comments	

Section: Unused_Study_Pro	5 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 01-06-2007	Entry Time: 10-10-2007 21:21:40	
Entered By: Sharon Ladenes	Last Modification Time: 08-01-2008 18:42:33	Page number: 25	
Unused Study Product Returned			
Product Returned	Flavor	Packs	Amount Returned Individual Cigarettes / pouches

Section: Study_Prod_Dispe	6 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 01-06-2007	Entry Time: 10-10-2007 21:21:40	
Entered By: Sharon Ladenes	Last Modification Time: 08-01-2008 18:42:33	Page number: 25	
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRF Report for Study E6270229

Patient: 2015

CRF: Week 4

Visit: WEEK 4

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 14-06-2007

Entry Time: 10-10-2007 21:23:23

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 10

Document #: R161217913

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 14-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:23	
		Last Modification Time:	
		Page number: 26	
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: Hdyl_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 14-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:23	
		Last Modification Time:	
		Page number: 26	
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 4		Section Date: 14-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:23	
		Last Modification Time:	
		Page number: 26	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic Diastolic		Oral Temperature xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 14-06-2007	

CRF Report for Study E6270229

Patient: 2015
CRF: Week 4
Visit: WEEK 4

Site: CD_001
Blank? Y
Visit Date: 14-06-2007

Investigator: RR_001
CRF Page #: 10
Document #: R161217913

Section: Expired_Carbon_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:23:23

Last Modification Time:

Page number: 26

EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
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Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 14-06-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:23:23

Last Modification Time:

Page number: 27

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 4

Section Date: 14-06-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:23:23

Last Modification Time:

Page number: 27

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 2015

CRF: Week 6

Visit: WEEK 6

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 28-06-2007

Entry Time: 10-10-2007 21:23:35

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 11

Document #: R161218113

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 28-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:35	
		Last Modification Time:	
		Page number: 28	
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 6		Section Date: 28-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:35	
		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: 28-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:35	
		Last Modification Time:	
		Page number: 28	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	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: 28-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:35	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2015
CRF: Week 6
Visit: WEEK 6

Site: CD_001
Blank? Y
Visit Date: 28-06-2007

Investigator: RR_001
CRF Page #: 11
Document #: R161218113

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: 28-06-2007

Entered By: Sharon Ladenaes

Entry Time: 10-10-2007 21:23:35

Last Modification Time:

Page number: 29

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 2015

CRF: Week 8

Visit: WEEK 8

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 12-07-2007

Entry Time: 10-10-2007 21:23:43

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 13

Document #: R161218213

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 12-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:43	
		Last Modification Time:	
		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

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 12-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:43	
		Last Modification Time:	
		Page number: 30	
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 8		Section Date: 12-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:43	
		Last Modification Time:	
		Page number: 30	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 12-07-2007	

CRF Report for Study E6270229

Patient: 2015

Site: CD_001

Investigator: RR_001

CRF: Week 8

Blank? Y

CRF Page #: 13

Visit: WEEK 8

Visit Date: 12-07-2007

Document #: R161218213

Section: Expired_Carbon_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:23:43

Last Modification Time:

Page number: 30

EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
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Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 12-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:23:43

Last Modification Time:

Page number: 31

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 8

Section Date: 12-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:23:43

Last Modification Time:

Page number: 31

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 2015

CRF: Week 10

Visit: WEEK 10

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 26-07-2007

Entry Time: 10-10-2007 21:23:53

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 14

Document #: R161218313

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 26-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:53	
		Last Modification Time:	
		Page number: 32	
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 10		Section Date: 26-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:53	
		Last Modification Time:	
		Page number: 32	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 26-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:53	
		Last Modification Time:	
		Page number: 32	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 26-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:23:53	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 10

Visit: WEEK 10

Site: CD_001

Blank? Y

Visit Date: 26-07-2007

Investigator: RR_001

CRF Page #: 14

Document #: R161218313

Section: Unused_Study_Pro

4 of 5

Page number: 33

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 10

Section Date: 26-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:23:53

Last Modification Time:

Page number: 33

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229

Patient: 2015

CRF: Week 12

Visit: WEEK 12

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 09-08-2007

Entry Time: 10-10-2007 21:24:01

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 15

Document #: R161218413

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 34	
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 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 34	
Drug Screen			
Date	Drug Screen Result		

Section: Alcohol_Screen	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 34	
Alcohol Screen			
Date	Breathalyzer Result		

Section: Preg_Test	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 34	
Pregnancy Test			

CRF Report for Study E6270229

Patient: 2015
CRF: Week 12
Visit: WEEK 12

Site: CD_001
Blank? Y
Visit Date: 09-08-2007

Investigator: RR_001
CRF Page #: 15
Document #: R161218413

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 34	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
			Comments

Section: Hdyf_Oral_Health	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 35	
HDYF? INQUIRY			
Date	Actual Time	HDYF Performed?	Comments

Section: Vital	7 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 35	
VITAL SIGNS			
		Blood Pressure	Oral Temperature
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
			Unit
			xxx.x
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 09-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:01	
		Last Modification Time:	
		Page number: 35	
ORAL HEALTH EXAMINATION			

CRF Report for Study E6270229

Patient: 2015
CRF: Week 12
Visit: WEEK 12

Site: CD_001
Blank? Y
Visit Date: 09-08-2007

Investigator: RR_001
CRF Page #: 15
Document #: R161218413

Section: Oral_Health_Exam	8 of 11		
Date	Procedure	Relevant Findings?*	Findings

Section: Phys_Exam	9 of 11	Blank? Y	Section Status: Created	
Visit: WEEK 12	Section Date: 09-08-2007	Entry Time: 10-10-2007 21:24:01		
Entered By: Sharon Ladenes	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: 09-08-2007	Entry Time: 10-10-2007 21:24:01		
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 36		
WEIGHT & HEIGHT				
Date	Weight xxx.x	Unit	Height xxx.x	Unit

Section: Lab_Eval	11 of 11	Blank? Y	Section Status: Created	
Visit: WEEK 12	Section Date: 09-08-2007	Entry Time: 10-10-2007 21:24:01		
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 37		
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

CRF Report for Study E6270229

Patient: 2015

CRF: Week 12(2)

Visit: WEEK 12

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 14:30:05

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 16

Document #: R169064813

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:05	
		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: 00-00-	
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:05	
		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: 00-00-	
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:05	
		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: 00-00-	
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:05	
		Last Modification Time:	
		Page number: 38	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
	Actual Time		

CRF Report for Study E6270229

Patient: 2015

CRF: Week 12(2)

Visit: WEEK 12

Site: CD_001

Blank? Y

Visit Date: 00-00-

Investigator: RR_001

CRF Page #: 16

Document #: R169064813

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 Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 06-12-2007 14:30:05	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 38	

PROVENTIL ADMINISTRATION			
Date	Actual Time of Proventil Administration	Amount Administered	Comments

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 06-12-2007 14:30:05	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 38	

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 12	Section Date: 00-00-	Entry Time: 06-12-2007 14:30:05	
Entered By: Sharon Ladenes	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 Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 06-12-2007 14:30:05	
Entered By: Sharon Ladenes			

CRF Report for Study E6270229

Patient: 2015
CRF: Week 12(2)
Visit: WEEK 12

Site: CD_001
Blank? Y
Visit Date: 00-00-

Investigator: RR_001
CRF Page #: 16
Document #: R169064813

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
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Section: Used_Study_Burn 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 00-00-

Entered By: Sharon Ladenes

Entry Time: 06-12-2007 14:30:05

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
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Section: Used_Butt_Measur 10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 00-00-

Entered By: Sharon Ladenes

Entry Time: 06-12-2007 14:30:05

Last Modification Time:

Page number: 42

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
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Section: Used_Butt_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 00-00-

Entered By: Sharon Ladenes

Entry Time: 06-12-2007 14:30:05

Last Modification Time:

Page number: 43

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
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CRF Report for Study E6270229



Patient: 2015

CRF: Week 12(3)

Visit: WEEK 12

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 14:30:10

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 17

Document #: R169064913

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:10	
		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: 00-00-	
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:10	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed

CRF Report for Study E6270229

Patient: 2015

CRF: Week 14

Visit: WEEK 14

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 23-08-2007

Entry Time: 10-10-2007 21:24:15

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 18

Document #: R161218613

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 23-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:15	
		Last Modification Time:	
		Page number: 45	
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 14		Section Date: 23-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:15	
		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: 23-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:15	
		Last Modification Time:	
		Page number: 45	
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 14		Section Date: 23-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:15	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 14

Visit: WEEK 14

Site: CD_001

Blank? Y

Visit Date: 23-08-2007

Investigator: RR_001

CRF Page #: 18

Document #: R161218613

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: 23-08-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:24:15

Last Modification Time:

Page number: 46

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229

Patient: 2015

CRF: Week 16

Visit: WEEK 16

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 06-09-2007

Entry Time: 10-10-2007 21:24:24

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 19

Document #: R161218713

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 06-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:24	
		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: 06-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:24	
		Last Modification Time:	
		Page number: 47	
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 16		Section Date: 06-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:24:24	
		Last Modification Time:	
		Page number: 47	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 06-09-2007	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 16

Visit: WEEK 16

Site: CD_001

Blank? Y

Visit Date: 06-09-2007

Investigator: RR_001

CRF Page #: 19

Document #: R161218713

Section: Expired_Carbon_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:24:24

Last Modification Time:

Page number: 47

EXPIRED CARBON MONOXIDE

Actual Time	ECO Level (ppm)	%COHb	Comments
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Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 06-09-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:24:24

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: 06-09-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:24:24

Last Modification Time:

Page number: 48

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 2015

CRF: Week 18

Visit: WEEK 18

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 20-09-2007

Entry Time: 10-10-2007 21:25:05

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 20

Document #: R161218913

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 20-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:25:05	
		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: 20-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:25:05	
		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: 20-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:25:05	
		Last Modification Time:	
		Page number: 49	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 20-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:25:05	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 18

Visit: WEEK 18

Site: CD_001

Blank? Y

Visit Date: 20-09-2007

Investigator: RR_001

CRF Page #: 20

Document #: R161218913

Section: Unused_Study_Pro 4 of 5

Page number: 50

Unused Study Product Returned

Product Returned		Amount Returned	
	Flavor	Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 18

Section Date: 20-09-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:25:05

Last Modification Time:

Page number: 50

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
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CRF Report for Study E6270229

Patient: 2015

CRF: Week 20

Visit: WEEK 20

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 04-10-2007

Entry Time: 10-10-2007 21:25:15

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 21

Document #: R161219013

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 04-10-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:25:15	
		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: 04-10-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:25:15	
		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: 04-10-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 21:25:15	
		Last Modification Time:	
		Page number: 51	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Oral Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 04-10-2007	

CRF Report for Study E6270229

Patient: 2015
CRF: Week 20
Visit: WEEK 20

Site: CD_001
Blank? Y
Visit Date: 04-10-2007

Investigator: RR_001
CRF Page #: 21
Document #: R161219013

Section: Expired_Carbon_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:25:15

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: 04-10-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:25:15

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: 04-10-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:25:15

Last Modification Time:

Page number: 52

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
-------------	-------------------	--------	------------------

CRF Report for Study E6270229

Patient: 2015

CRF: Week 22

Visit: WEEK 22

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 18-10-2007

Entry Time: 06-12-2007 14:30:30

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 22

Document #: R169065213

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created				
Visit: WEEK 22		Section Date: 18-10-2007					
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:30					
		Last Modification Time:					
		Page number: 53					
<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 22		Section Date: 18-10-2007					
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:30					
		Last Modification Time:					
		Page number: 53					
<p>EXPIRED CARBON MONOXIDE</p> <table border="1"> <thead> <tr> <th>Actual Time</th> <th>ECO Level (ppm)</th> <th>%COHb</th> <th>Comments</th> </tr> </thead> </table>				Actual Time	ECO Level (ppm)	%COHb	Comments
Actual Time	ECO Level (ppm)	%COHb	Comments				

Section: Vital	3 of 5	Blank? Y	Section Status: Created														
Visit: WEEK 22		Section Date: 18-10-2007															
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:30															
		Last Modification Time:															
		Page number: 53															
<p>VITAL SIGNS</p> <table border="1"> <thead> <tr> <th>Actual Time</th> <th>Blood Pressure</th> <th></th> <th>Pulse</th> <th>Respiratory Rate</th> <th>Oral Temperature</th> <th>Unit</th> </tr> <tr> <th></th> <th>Systolic</th> <th>Diastolic</th> <th></th> <th></th> <th>xxx.x</th> <th></th> </tr> </thead> </table> <p>Comments</p>				Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit		Systolic	Diastolic			xxx.x	
Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit											
	Systolic	Diastolic			xxx.x												

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 18-10-2007	
Entered By: Sharon Ladenes		Entry Time: 06-12-2007 14:30:30	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 22

Visit: WEEK 22

Site: CD_001

Blank? Y

Visit Date: 18-10-2007

Investigator: RR_001

CRF Page #: 22

Document #: R169065213

Section: Unused_Study_Pro 4 of 5

Page number: 54

Unused Study Product Returned

Product Returned		Amount Returned	
	Flavor	Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 22

Section Date: 18-10-2007

Entered By: Sharon Ladenes

Entry Time: 06-12-2007 14:30:30

Last Modification Time:

Page number: 54

STUDY PRODUCT DISPENSATION

Actual Time	Product Dispensed	Flavor	Amount Dispensed
-------------	-------------------	--------	------------------

CRF Report for Study E6270229



Patient: 2015
CRF: Week 24 (Eos)
Visit: WEEK 24 (EOS)
Entered By: Sharon Ladenes
Discrepancies: Closed
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 16-07-2007
Entry Time: 18-09-2007 14:38:14
Modification Time: 09-01-2008 18:18:26
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 23
Document #: R157128713
CRF Status: Entry Complete

Approver:
Verifier:

Section: Pro_Questionnaire	1 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:38:14	
		Last Modification Time: 18-09-2007 14:40:21	
		Page number: 55	

Date	PRO QUESTIONNAIRES	YES / NO
16-07-2007	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 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:38:14	
		Last Modification Time: 18-09-2007 14:40:21	
		Page number: 55	

Date	Drug Screen	Drug Screen Result
16-07-2007		ND

Section: Alcohol_Screen	3 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:38:14	
		Last Modification Time: 11-12-2007 12:26:48	
		Page number: 55	

Date	Alcohol Screen	Breathalyzer Result
16-07-2007		NEG

Section: Preg_Test	4 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:38:14	
		Last Modification Time: 11-12-2007 12:27:13	
		Page number: 55	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Investigator: RR_001

CRF Page #: 23

Document #: R157128713

Section: Preg_Test 4 of 12

Pregnancy Test

Date	Result
16-07-2007	NEGA TIVE

Section: Urine_Coll 5 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:38:14

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? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:38:14

Last Modification Time: 18-09-2007 14:44:32

Page number: 56

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time	Ventricular Heart Rate
1511	093

Cardiac Cycle Measurements

PR Interval	QRS Duration	QT Interval	QTc Interval
152	075	352	438

ECG INTERPRETATION:

ANCS

Comments (related to abnormal, CS findings only):

Section: Hdyf_Oral_Health 7 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:38:14

Last Modification Time: 08-01-2008 18:46:03

Page number: 57

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Date	Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
------	-------------	-----------------	----------------------------------	----------

CRF Report for Study E6270229

Patient: 2015

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Investigator: RR_001

CRF Page #: 23

Document #: R157128713

Section: Hdyf_Oral_Health	7 of 12		
16-07-2007	NR	YES	YES

Section: Vital	8 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:38:14	
		Last Modification Time: 18-09-2007 14:45:43	
		Page number: 57	

VITAL SIGNS							
Blood Pressure							
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
16-07-2007	1502	091	057	090	14	036.6	C
						xxx.x	
Comments							

Section: Oral_Health_Exam	9 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:38:14	
		Last Modification Time: 09-01-2008 18:17:24	
		Page number: 57	

ORAL HEALTH EXAMINATION			
Date	Procedure	Relevant Findings?*	Findings
16-07-2007	ORAL HEALTH QUESTIONS PERFORMED	NO	
	EVIDENCE OF LEUKOPLAKIA	NE	
	OTHER ORAL KERATOSIS	NE	

Section: Phys_Exam	10 of 12	Blank? Y	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:38:14	
		Last Modification Time: 09-01-2008 18:18:26	
		Page number: 58	

PHYSICAL EXAMINATION				
Date	Code Number	Code	Relevant Findings?	Findings

Section: Weight_Height	11 of 12	Blank? N	Section Status: Entry Complete
WEEK 24 (EOS)		16-07-2007	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Investigator: RR_001

CRF Page #: 23

Document #: R157128713

Section: Weight_Height 11 of 12

Visit:

Section Date:

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:38:14

Last Modification Time: 18-09-2007 14:47:24

Page number: 58

WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
16-07-2007	131.0	KG	ND	CM
	xxx.x		xxx.x	

Section: Lab_Eval 12 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:38:14

Last Modification Time: 18-09-2007 14:48:02

Page number: 59

Laboratory Evaluations

Date

16-07-2007

Were the scheduled laboratory samples obtained?

YES

No, specify

Requisition Number 1

N528087

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: 2015

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Entry Time: 18-09-2007 14:48:12

Modification Time: 08-10-2007 17:30:19

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 24

Document #: R157139313

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		Last Modification Time: 18-09-2007 14:53:09	
		Page number: 59	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
16-07-2007	1519		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		Last Modification Time: 18-09-2007 14:53:09	
		Page number: 59	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
16-07-2007	1536	11	02.3

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		Last Modification Time: 18-09-2007 14:53:09	
		Page number: 59	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
16-07-2007	1519		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		Last Modification Time: 18-09-2007 14:53:09	
		Page number: 60	

CRF Report for Study E6270229

Patient: 2015

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Investigator: RR_001

CRF Page #: 24

Document #: R157139313

Section: Pre_Bronch_Spir 4 of 11

PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT

Date	Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
16-07-2007	1529	STANDI NG	2.77	101	3.58	107	

Section: Proventil_Admin 5 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:48:12

Last Modification Time: 18-09-2007 14:53:09

Page number: 60

PROVENTIL ADMINISTRATION

Date	Actual Time of Proventil Administration	Amount Administered	Comments
16-07-2007	ND	NA	

Section: Post_Bronch_Spir 6 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:48:12

Last Modification Time:

Page number: 60

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: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:48:12

Last Modification Time:

Page number: 61

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
-----------------------------------	------------	------------	--------------	--------------	---	--	---------------------------	-----------------------------	----------

CRF Report for Study E6270229

Patient: 2015

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Investigator: RR_001

CRF Page #: 24

Document #: R157139313

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		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: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		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: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		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: 16-07-2007	
Entered By: Sharon Ladenes		Entry Time: 18-09-2007 14:48:12	
		Last Modification Time:	
		Page number: 65	

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Date	Scheduled Collection Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
------	-----------------------------	-----------------------	---------------------------------

CRF Report for Study E6270229

Patient: 2015

CRF: Week 24-3

Visit: WEEK 24 (EOS)

Entered By: Sharon Ladenaes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Entry Time: 18-09-2007 14:53:10

Modification Time: 09-01-2008 18:20:27

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 25

Document #: R157144613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Unused_Study_Pro

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 16-07-2007

Entered By: Sharon Ladenaes

Entry Time: 18-09-2007 14:53:10

Last Modification Time: 09-01-2008 18:20:27

Page number: 65A

Unused Study Product Returned

Date	Actual Time	Product Returned	Flavor	Amount Returned	
				Packs	Individual Cigarettes / pouches
16-07-2007	NR	SNUS	FROST	00	00
16-07-2007	NR	SNUS	SPICE	00	2
16-07-2007	NR	SNUS	ORIGINAL	0	0

CRF Report for Study E6270229

Patient: 2015

CRF: Precon_Med

Visit: PRECON_MEDS

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 16-05-2007

Entry Time: 18-09-2007 14:56:23

Modification Time: 18-09-2007 20:48:00

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 26

Document #: R157147413

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pre_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON_MEDS

Section Date: 16-05-2007

Entered By: Sharon Ladenes

Entry Time: 18-09-2007 14:56:23

Last Modification Time: 18-09-2007 14:57:53

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?

YES

Seq #	Drug Name	Indication	Dose / Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing
1	THERAFLU NIGHTIME	COLD PREVENTIVE	UNKNOWN	PO		ONCE		16-05-2007	16-05-2007

CRF Report for Study E6270229

Patient: 2015

CRF: AE

Visit: AE

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 16-07-2007

Entry Time: 10-10-2007 21:25:56

Modification Time: 10-10-2007 21:26:23

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 27

Document #: R161219313

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ae_Med

Blank? N

Section Status: Entry Complete

Visit: AE

Section Date: 16-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:25:56

Last Modification Time: 10-10-2007 21:26:23

Page number: 67

Adverse Events

Did the subject experience any adverse events?

NO

Onset

Resolved/Changed

Serious

Relationship to

Procedure

Action

Outcome

Event No.

Adverse Event

Date

Time

Date

Time

Event?

Severity

Product

Taken

to Date

CRF Report for Study E6270229

Patient: 2015

CRF: Ecg_Unscheduled

Visit: ECG_UNSCHE

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 00-00-

Entry Time: 10-10-2007 21:26:30

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 28

Document #: R161219613

CRF Status: Created

Approver:

Verifier:

Section: ECG

Blank? Y

Section Status: Created

Visit: ECG_UNSCHE

Section Date: 00-00-

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:26:30

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: 2015

CRF: Lab_Unscheduled

Visit: LAB_UNSCHE

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? N

Visit Date: 03-05-2007

Entry Time: 06-07-2007 10:58:44

Modification Time: 06-01-2008 18:02:28

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 29

Document #: R147698813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Lab_Eval

Blank? N

Section Status: Entry Complete

Visit: LAB_UNSCHE

Section Date: 03-05-2007

Entered By: Sharon Ladenes

Entry Time: 06-07-2007 10:58:44

Last Modification Time: 06-01-2008 18:02:28

Page number: 69

Unscheduled Laboratory Evaluations

Clinically

If Clinically Significant, Specify

Date	Requisition Number	Clinically Significant?	Test Name	High(H)/Low(L)	Lab ID	Lab Name	Comments
03-05-2007	O410268	NO					

CRF Report for Study E6270229

Patient: 2015

CRF: Vital_Unscheduled

Visit: VITAL_UNSCHEDED

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 00-00-

Entry Time: 10-10-2007 21:26:59

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 30

Document #: R161220113

CRF Status: Created

Approver:

Verifier:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL_UNSCHEDED

Section Date: 00-00-

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:26:59

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		

CRF Report for Study E6270229

Patient: 2015

CRF: Stdy_Prdt_Dis_Unscheduled

Visit: STDY_PRDT_UNSCHE

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 01-06-2007

Entry Time: 10-10-2007 21:26:43

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 31

Document #: R161219813

CRF Status: Created

Approver:

Verifier:

Section: Study_Prod_Dispe

Blank? Y

Section Status: Created

Visit: STDY_PRDT_UNSCHE

Section Date: 01-06-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:26:43

Last Modification Time:

Page number: 71

UNSCHEDULED STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed	Comments
------	-------------	-------------------	--------	------------------	----------

CRF Report for Study E6270229

Patient: 2015

CRF: Expired_Co2_Unscheduled

Visit: EXPIRED_CO2_UNSC

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD_001

Blank? Y

Visit Date: 00-00-

Entry Time: 10-10-2007 21:27:23

Modification Time:

Approval Time:

Verification Time:

Investigator: RR_001

CRF Page #: 32

Document #: R161220313

CRF Status: Created

Approver:

Verifier:

Section: Expired_Carbon_M

Blank? Y

Section Status: Created

Visit: EXPIRED_CO2_UNSC

Section Date: 00-00-

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:27:23

Last Modification Time:

Page number: 72

UNSCHEDULED EXPIRED CARBON MONOXIDE

Date	Actual Time	ECO Level (ppm)	%COHb	Comments
------	-------------	-----------------	-------	----------

CRF Report for Study E6270229

Patient: 2015

Site: CD_001

Investigator: RR_001

CRF: Oral_Health_Unscheduled

Blank? Y

CRF Page #: 33

Visit: ORAL_HEALTH_UNSC

Visit Date: 00-00-

Document #: R161220413

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:27:27

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Oral_Health_Exam	Blank? Y	Section Status: Created
Visit: ORAL_HEALTH_UNSC	Section Date: 00-00-	
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 21:27:27	
	Last Modification Time:	
	Page number: 73	

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

CRF Report for Study E6270229

Patient: 2015

Site: CD_001

Investigator: RR_001

CRF: Spirometry_Unscheduled

Blank? Y

CRF Page #: 34

Visit: SPIRO_TEST_UNSCH

Visit Date: 00-00-

Document #: R161220513

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 21:27:31

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: Sharon Ladenes

Entry Time: 10-10-2007 21:27:31

Last Modification Time:

Page number: 74

UNSCHEDULED SPIROMETRY TEST RESULT

Date	Actual Time of FEV1/FVC Test	Testing Position	Timepoint based on Proventil Administration	Proventil Administration (and time of Administration)	(Time)	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
------	------------------------------------	---------------------	---	--	---------	--------	--------------------------	-------	-------------------------	----------

CRF Report for Study E6270229



Patient: 2015
CRF: Study_Completion
Visit: STUDY_COMP
Entered By: Sharon Ladenaes
Discrepancies: None
Approval Status: Not Approved
Verification: Not Verified
Comment:

Site: CD_001
Blank? N
Visit Date: 16-07-2007
Entry Time: 18-09-2007 14:58:15
Modification Time: 18-09-2007 14:58:40
Approval Time:
Verification Time:

Investigator: RR_001
CRF Page #: 35
Document #: R157149113
CRF Status: Entry Complete

Approver:
Verifier:

Section: Study_Comp	Blank? N	Section Status: Entry Complete
Visit: STUDY_COMP	Section Date: 16-07-2007	
Entered By: Sharon Ladenaes	Entry Time: 18-09-2007 14:58:15	
	Last Modification Time: 18-09-2007 14:58:40	
	Page number: 75	

Study Completion	
Did the subject complete the study?	NO
Date the subject completed OR withdrew from the study:	16-07-2007
Reason for Withdrawal	CONSENT
Specify	
Investigator Comments	
Principal Investigator	Date 11 Jan 2008

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N526978

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.
c/o Mark Schambura
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

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.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

Investigator Signature:

Date:

B18097

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LABORATORY REPORT

ACCESSION NO. N526978

Page 1 of 3

INVESTIGATOR: (B18097)

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.4		0.2-1.2 mg/dL
Alk Phos	111	H	31-106 U/L
ALT (SGPT)	7		6-34 U/L
AST (SGOT)	13		9-34 U/L
GGT	25		4-49 U/L
LDH	166		53-234 U/L
Urea Nitr	14		4-24 mg/dL
Creatinine	0.8		0.4-1.1 mg/dL
Glucose	83		70-115 mg/dL
Uric Acid	3.3		2.1-7.2 mg/dL
Calcium	9.6		8.3-10.6 mg/dL
Phosphorus	4.6		2.2-5.1 mg/dL
Total Prot	6.8		6.1-8.4 g/dL
Albumin	3.8		3.3-4.9 g/dL
Sodium	143		132-147 mEq/L
Potassium	4.5		3.4-5.4 mEq/L
Chloride	106		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

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ACCESSION NO. N526978

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INVESTIGATOR: (B18097)

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
 Significant/ Adverse
 Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	12.1	11.6-16.4 g/dL
HCT	38	34-48 %
RBC	4.5	4.1-5.6x10 ⁶ /uL
MCV	83	79-98 fL
MCH	27	26-34 pg
MCHC	32	31-38 g/dL
RDW	15.1 H	12.0-15.0 %
RBC Morph	Normocytic	
WBC	9.75	3.80-10.70 x10 ³ /uL
Neutrophil	6.68	1.96-7.23 x10 ³ /uL
Lymphocyte	2.56	0.91-4.28 x10 ³ /uL
Monocytes	0.37	0.12-0.92 x10 ³ /uL
Eosinophil	0.10	0.00-0.57 x10 ³ /uL
Basophils	0.03	0.00-0.20 x10 ³ /uL
Neutrophil	68.5	40.5-75.0 %
Lymphocyte	26.3	15.4-48.5%
Monocytes	3.8	2.6-10.1 %
Eosinophil	1.1	0.0-6.8 %
Basophils	0.3	0.0-2.0 %
Platelets	297	140-400 x10 ³ /uL

[]

[]

Investigator Signature:

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/T/11/1

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LABORATORY REPORT

ACCESSION NO. N526978

Page 3 of 3

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

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	1.012	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	Positive	

MISCELLANEOUS ELEMENTS

Mucous	Present	Ref Rng: Not present
--------	---------	----------------------

Investigator Signature:

Date:

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LABORATORY REPORT

ACCESSION NO. N526978

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Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 2
RANDOMIZATION NUMBER: R2015
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0
COLLECTION TIME: 06:12 DATE: 18-May-2007
DATE RECEIVED IN LABORATORY: 19-May-2007
DATE REPORTED BY LABORATORY: 19-May-2007
SEX: F BIRTHDATE: (b) (6) AGE: 40
SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes No

TOTAL IRON
Total Iron 67 30-160 ug/dL

C-REACTIVE PROTEIN
CRP-HS 0.540 H <=0.287 mg/dL [] []

CARBOXYHEMOGLOBIN
Carboxyhem 3.0 % saturation
No Ref Rng

QCD

8/18/07

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

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/TUN

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LABORATORY REPORT

ACCESSION NO. N526978

Page 1 of 1

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SPONSOR REPORT TO:

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3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 23-May-2007

SEX: F BIRTHDATE: [REDACTED] AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

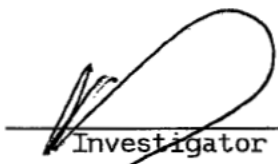
Yes

No

LIPID PANEL

Triglycer	73	45-214 mg/dL
Cholest	211	155-265 mg/dL
HDL Dex-S	60	34-88 mg/dL
LDL Chol	136	74-174 mg/dL

AS 18 May 2007



Investigator Signature:

17 Jul 2007
Date:

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LABORATORY REPORT

ACCESSION NO. N526978
Page 1 of 1

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Dallas, TX 75247
SPONSOR REPORT TO:
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Medical Director
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3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 2
RANDOMIZATION NUMBER: R2015
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0
COLLECTION TIME: 06:12 DATE: 18-May-2007
DATE RECEIVED IN LABORATORY: 19-May-2007
DATE REPORTED BY LABORATORY: 19-May-2007
SEX: F BIRTHDATE: (b) (6) AGE: 40
SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?
Yes No

HOMOCYSTEINE
*1 HCY 7.21 3.36-20.44 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:

Date:

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LABORATORY REPORT

ACCESSION NO. N526978

Page 1 of 1

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Dallas, TX 75247

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMOGLOBIN A1C

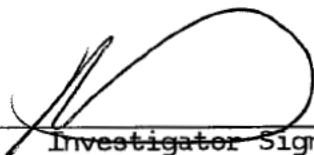
Hgb A1c 6.0

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%



Investigator Signature:

18858612007



Date:

Covance CLS

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Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526978

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.
c/o Mark Schambura
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

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.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

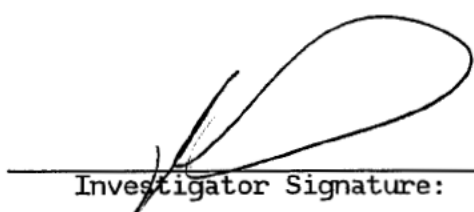
No

FIBRINOGEN

Fibrinogen 464 H 200-400 mg/dL

[]

[]


Investigator Signature:

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

B18097

Covance CLS
Marietta Henry, M.D., Director
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LABORATORY REPORT

ACCESSION NO. N526978
Page 1 of 1

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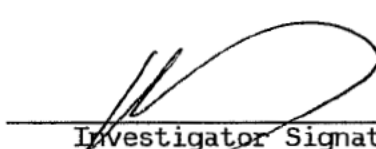
SPONSOR REPORT TO:
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Medical Director
Covance CRU, Inc.
3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 2
RANDOMIZATION NUMBER: R2015
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0
COLLECTION TIME: 06:12 DATE: 18-May-2007
DATE RECEIVED IN LABORATORY: 19-May-2007
DATE REPORTED BY LABORATORY: 20-May-2007
SEX: F BIRTHDATE: (b) (6) AGE: 40
SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?
Yes No

URINE CREATININE, SPOT
Rnd Ur Crt 93 mg/dL No Ref Rng


Investigator Signature:


Date:

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T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

B18097

(TNV)

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LABORATORY REPORT

ACCESSION NO. N526978

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Dallas, TX 75247

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

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

Investigator Signature:

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

B18097

/TNUV

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LABORATORY REPORT

ACCESSION NO. N526978

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1

sICAM-1

291

115-306 ng/mL

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

B18097

Covance CLS

Marietta Henry, M.D., Director
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Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. N526978

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.
c/o Mark Schambura
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

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.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:12 DATE: 18-May-2007

DATE RECEIVED IN LABORATORY: 19-May-2007

DATE REPORTED BY LABORATORY: 19-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 40

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)
Wash/Store Completed

Investigator Signature:

Date:

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B18097

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N528087

Page 1 of 1

INVESTIGATOR: (B18097)

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Dallas, TX 75247

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 15:19 DATE: 16-Jul-2007

DATE RECEIVED IN LABORATORY: 17-Jul-2007

DATE REPORTED BY LABORATORY: 17-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

No

CC'D

28 30 AUG 2007

Investigator Signature:

Date:

B18097

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N528087

Page 1 of 3

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PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 15:19 DATE: 16-Jul-2007

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SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.4	0.2-1.2 mg/dL
Alk Phos	86	31-106 U/L
ALT (SGPT)	12	6-34 U/L
AST (SGOT)	17	9-34 U/L
GGT	26	4-49 U/L
LDH	149	53-234 U/L
Urea Nitr	9	4-24 mg/dL
Creatinine	0.9	0.4-1.1 mg/dL
Glucose	85	70-115 mg/dL
Uric Acid	3.7	2.1-7.2 mg/dL
Calcium	9.5	8.3-10.6 mg/dL
Phosphorus	3.5	2.2-5.1 mg/dL
Total Prot	6.5	6.1-8.4 g/dL
Albumin	3.8	3.3-4.9 g/dL
Sodium	144	132-147 mEq/L
Potassium	4.1	3.4-5.4 mEq/L
Chloride	106	94-112 mEq/L

QC'D

8/30/07

Investigator Signature:

94 Jul 2007
Date:

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N528087

Page 2 of 3

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PROTOCOL 6270-229

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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	12.1		11.6-16.4 g/dL
HCT	34		34-48 %
RBC	4.2		4.1-5.6x10 ⁶ /uL
MCV	82		79-98 fL
MCH	29		26-34 pg
MCHC	35		31-38 g/dL
RDW	15.8	H	12.0-15.0 %
RBC Morph	Normocytic		
WBC	11.41	H	3.80-10.70 x10 ³ /uL
Neutrophil	7.49	H	1.96-7.23 x10 ³ /uL
Lymphocyte	3.21		0.91-4.28 x10 ³ /uL
Monocytes	0.54		0.12-0.92 x10 ³ /uL
Eosinophil	0.12		0.00-0.57 x10 ³ /uL
Basophils	0.05		0.00-0.20 x10 ³ /uL
Neutrophil	65.6		40.5-75.0 %
Lymphocyte	28.2		15.4-48.5 %
Monocytes	4.7		2.6-10.1 %
Eosinophil	1.1		0.0-6.8 %
Basophils	0.5		0.0-2.0 %
Platelets	296		140-400 x10 ³ /uL

[]

[]

[]

[]

[]

[]

QC'D

Investigator Signature:

Date:

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B18097

/TAM/

Covance CLS

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LABORATORY REPORT

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 15

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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow
Clarity	Clear
Spec Grav	1.009
pH	6.0
Protein	Negative
Glucose	Normal
Ketones	Negative
Bilirubin	Negative
Urobilin	Normal
Blood	Negative
Nitrite	Negative
Leuk Est	Negative
Microscop	Positive

Ref Rng:
Colorless or Yellow
Ref Rng: Clear
1.003-1.035
5.0-8.0
Ref Rng: Negative
Ref Rng: Normal
Ref Rng: Negative
Ref Rng: Negative
Ref Rng: Normal
Ref Rng:
Negative-Trace
Ref Rng: Negative
Ref Rng: Negative

NCS R 21 May 2008

MISCELLANEOUS ELEMENTS

Mucous	Present
--------	---------

Ref Rng: Not present

QC'D

30 JUL 2007

Investigator Signature:

Date:

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B18097

(INV)

21 May 2008

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N528087

Page 3 of 3

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

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VISIT: 15

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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

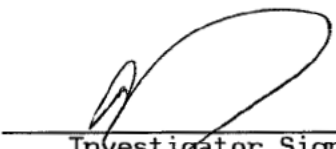
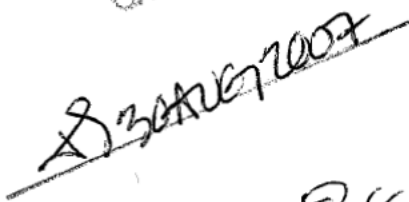
Color	Yellow
Clarity	Clear
Spec Grav	1.009
pH	6.0
Protein	Negative
Glucose	Normal
Ketones	Negative
Bilirubin	Negative
Urobilin	Normal
Blood	Negative
Nitrite	Negative
Leuk Est	Negative
Microscop	Positive

Ref Rng:
Colorless or Yellow
Ref Rng: Clear
1.003-1.035
5.0-8.0
Ref Rng: Negative
Ref Rng: Normal
Ref Rng: Negative
Ref Rng: Negative
Ref Rng: Normal
Ref Rng:
Negative-Trace
Ref Rng: Negative
Ref Rng: Negative

MISCELLANEOUS ELEMENTS

Mucous Present

Ref Rng: Not present


Investigator Signature:
Date:

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

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SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

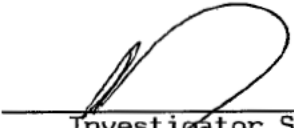
Total Iron 61 30-160 ug/dL

C-REACTIVE PROTEIN

CRP-HS 0.283 <=0.287 mg/dL

CARBOXYHEMOGLOBIN

Carboxyhem 3.6 % saturation
No Ref Rng


Investigator Signature:


Date:

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LABORATORY REPORT

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Page 1 of 1

INVESTIGATOR: (B18097)

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Dallas, TX 75247

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 15:19 DATE: 16-Jul-2007

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DATE REPORTED BY LABORATORY: 17-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HOMOCYSTEINE

*1 HCY

7.00

3.36-20.44 umol/L

QC'D

28 30 AUG 2007

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.

[Signature]
Investigator Signature:

28 Jul 2007
Date:

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LABORATORY REPORT

ACCESSION NO. N528087
Page 1 of 1

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3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 2
RANDOMIZATION NUMBER: R2015
PATIENT INITIALS: (b) (6)
VISIT: 15
Week 24/Early Term
COLLECTION TIME: 15:19 DATE: 16-Jul-2007
DATE RECEIVED IN LABORATORY: 17-Jul-2007
DATE REPORTED BY LABORATORY: 17-Jul-2007
SEX: F BIRTHDATE: (b) (6) AGE: 41
SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?
Yes No

FIBRINOGEN
Fibrinogen 387 200-400 mg/dL

QC'D

AS 30 JUL 2007


Investigator Signature:

24 Jul 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

B18097

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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?
Yes No

URINE CREATININE, SPOT
Rnd Ur Crt 62 mg/dL No Ref Rng

QC'D

28 AUG 2007


Investigator Signature:

28 Jul 2007
Date:

Covance CLS

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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c 5.9

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%


Investigator Signature:


Date:

Covance CLS

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LABORATORY REPORT

**** REPRINTED: 05-OCT-2007 ****

ACCESSION NO. N528087

Page 1 of 1

INVESTIGATOR: (B18097)

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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

OXIDIZED LDL - See Note #1

Note #1 - No specimen received

Investigator Signature:

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

B18097

Date:

10 OCT 2007

QC'D

[Handwritten signature]

Covance CLS

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LABORATORY REPORT

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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

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

Investigator Signature:

H(High) or L(Low)=Values above or below reference range.

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

B18097

/TA001

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PROTOCOL 6270-229
INVESTIGATOR NO.: 2
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SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes No

LIPID PANEL - See Note #1

QC'D

Handwritten signature and date:
10 OCT 2007

Note #1 - No specimen received

Handwritten signature: ZP
Investigator Signature:

Handwritten date: 10 OCT 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

B18097

(TM)

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LABORATORY REPORT

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Is this Clinically
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Event?

Yes

No

LIPID PANEL - See Note #1

Note #1 - No specimen received

Investigator Signature:

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B18097

Date:

Covance CLS

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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.: 2

RANDOMIZATION NUMBER: R2015

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 15:19 DATE: 16-Jul-2007

DATE RECEIVED IN LABORATORY: 17-Jul-2007

DATE REPORTED BY LABORATORY: 30-Jul-2007

SEX: F BIRTHDATE: (b) (6) AGE: 41

SCREENING NUMBER: S2095

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1


sICAM-1

199

115-306 ng/mL

QC'D

AS 30 AUG 2007

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

B18097

/TMV/

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N528087

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.
c/o Mark Schambura
Radiant Research Inc
1341 W Mockingbird Ln/Ste 400E
Dallas, TX 75247

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Is this Clinically
Significant/ Adverse
Event?

Yes No

RBC CELL WASHING (4-ABP-HB) - See Note #1

QC'D

28 30 AUG 2007

Note #1 - Specimen severely hemolyzed - unable to perform test

Investigator Signature: _____

24 Jul 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

B18097