

age ID: D11548613

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin
Investigator:David Carter
ate:25-FEB-2008

Patient#:5001
Patient Initials:
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
TC Tar level of Usual Brand SCREENING Disc ID: 1314577713 Type: UNIVARIATE	3 21MAR07 Closed: N	Value for FTC Tar Level has not been supplied for the Screening timepoint.	10.7
Pregnancy Test WEEK 0 (BASELINE) Disc ID: 1317903613 Type: MANUAL	5 15APR07 Closed: N	Disc ID 1291628013 requested 'For consistency across site subjects and sites, please confirm that, although this is a Male subject, 'Pregnancy Test Date' should be populated with the visit date', however resolution was not provided.	<input checked="" type="checkbox"/> Date=15-04-2007 <input type="checkbox"/> Other: _____

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

Amanda Lynn
Authorized Personnel Signature
26-Feb-2008
Date

age ID: D11301113

/ Covance No. 6270-229

Data Clarification Form

o:Covance CRU Austin
investigator:David Carter
ate:28-JAN-2008

Patient#:5001
Patient Initials:
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
4-Hour Urine Collection WEEK 0 (BASELINE Disc ID: 1291159813 Type: MANUAL HEADER	15APR07 Closed: N	W0 24 hour urine collection lab req (#N528386) was not provided with this crf. Please forward with this dcf.	<input checked="" type="checkbox"/> Req attached <input type="checkbox"/> Other:_____
Pregnancy Test WEEK 0 (BASELINE Disc ID: 1291628013 Type: MANUAL	5 15APR07 Closed: N	For consistency across site subjects and sites, please confirm that, although this is a Male subject, 'Pregnancy Test Date' should be populated with the visit date.	<input type="checkbox"/> 15-04-2007 <input type="checkbox"/> Other:_____

DM2
621008

DM2
621008

Req. req. for resolution DM2 021008

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.

Amanda Lynn
Authorized Personnel Signature

29/Jan/2008
Date

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N528386

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6) 5011

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:40 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 17-Apr-2007

DATE REPORTED BY LABORATORY: 06-Sep-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1748

800-1800 mg/24hr

UAlq24Crea 72.0

mg/dL No Ref-Rng


24 HR COLLECTION INFORMATION

Start Date 15-Apr-2007

Start Time 15:26

Stop Date 16-Apr-2007

Stop Time 15:39


Investigator Signature:

28 Sep 07
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

B17181

(INV)

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LABORATORY REPORT

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6) 5011

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:40 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 17-Apr-2007

DATE REPORTED BY LABORATORY: 17-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes No


24 HR COLLECTION INFORMATION

Start Date 15-Apr-2007

Start Time 15:26

Stop Date 16-Apr-2007

Stop Time 15:40


Investigator Signature:

17 Aug 07
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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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6) 5011

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:40 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 17-Apr-2007

DATE REPORTED BY LABORATORY: 16-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

ELAPSED DATE AND TIME, 24HR

Elpsd D&T 1454 min


Investigator Signature:

17 Aug 07
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

B17181

(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N528386

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6) 5011

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:40 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 17-Apr-2007

DATE REPORTED BY LABORATORY: 31-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

ELAPSED DATE AND TIME, 24HR

Elpsd D&T 1453 min


Investigator Signature:

28 Sep 07
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

B17181

(INV)

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LABORATORY REPORT

ACCESSION NO. N528386

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6) 5011

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:40 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 17-Apr-2007

DATE REPORTED BY LABORATORY: 18-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No


URINE CREATININE, 24 HR

U24h Creat 1747

UAlq24Crea 72.0

800-1800 mg/24hr

mg/dL No Ref Rng


Investigator Signature:

30 Aug 07
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

B17181

(INV)

Covance CLS

age ID: D11301213

/ Covance No. 6270-229

Data Clarification Form

o: Covance CRU Austin
Investigator: David Carter
ate: 28-JAN-2008

Patient#: 5001
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Study Completion STUDY_COMP Disc ID: 1213391413 Type: MULTIVARIATE	35 16APR07 Closed: N	Specific reason is provided, but primary reason subject did not complete study product is <Consent Withdrawn>, for which 'specify' is not an option. Please reconcile.	<input checked="" type="checkbox"/> Delete comment/specify <input type="checkbox"/> Other: _____
Study Product Dispensation WEEK 0 (BASELINE) Disc ID: 1291174113 Type: MANUAL	5.2 16APR07 Closed: N	Study Product Dispensation 'Amount Dispensed' for the W0 visit currently presents '60'. This appears to be a count of the number of SNUS pouches. For consistency of other reported dispensations, please confirm this is '1' tub/packet.	<input checked="" type="checkbox"/> Amount Dispensed=1 <input type="checkbox"/> Other: _____

DM2
02/16/08

DM2
02/16/08

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Amanda Lynn
Authorized Personnel Signature

29/Jan/2008
Date

CRF Report for Study E6270229

Patient: 001

Site: CA_001

Investigator: C2785_03

CRF: Header_Page

Blank? N

CRF Page #: 1

Visit: SCREENING

Visit Date: 21-03-2007

Document #: R139467513

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:41:28

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 25-04-2007 15:44:26

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Header_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:41:28

Last Modification Time: 25-04-2007 15:44:26

Page number: 1

RDC CASE REPORT FORM

SMOKER

Sponsor Name

Investigator

Site

RJ REYNOLDS TOBACCO COMPANY

DAVID CARTER

CA_001

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: 5001

Site: CA_001

Investigator: C2785_03

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 21-03-2007

Document #: R139468513

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

CRF Status: Entry Started

Discrepancies: None

Modification Time: 21-09-2007 18:34:05

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Inc_Criteria

1 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 13-06-2007 05:04:02

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: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 25-04-2007 15:57:50

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 Eb210229

Patient: J001

CRF: Screening

Visit: SCREENING

Site: CA_001

Blank? N

Visit Date: 21-03-2007

Investigator: C2785_03

CRF Page #: 2

Document #: R139468513

Section: Inc_Criteria 2 of 10

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

Section: Exc_Criteria 3 of 10

Blank? N

Section Status: Created

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

Last Modification Time:

Page number: 3

Exclusion Criteria

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

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 21-03-2007

Document #: R139468513

Section: Informed Consent

4 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 25-04-2007 16:06:45

Page number: 4

Informed Consent

Date the Subject Signed the Smoker Informed Consent Form

21-03-2007

Section: Elig

5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 25-04-2007 16:06:45

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: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 25-04-2007 16:06:45

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: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 25-04-2007 16:18:30

Page number: 5

Demographics

Subject Initials

(b)

Date of Birth

Gender

Height

Height Unit

Weight

Weight Unit

(b) (6)

M

175.9

CM

97.2

KG

xxx.x

xxx.x

Ethnicity

CRF Report for Study E6210229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 21-03-2007

Document #: R139468513

Section: Demog

7 of 10

Hispanic or Latino?

NO

Race

WHITE

Race other

Section: Vital

8 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heven

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 25-04-2007 16:18:30

Page number: 5

VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit
1224	Systolic 122	Diastolic 80	77	18	35.7	C
					xxx.x	

Comments

Section: Hdyl_Oral_Health

9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heven

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 25-04-2007 16:18:30

Page number: 5

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
1140	YES	YES	

Section: Lab_Eval

10 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heven

Entry Time: 25-04-2007 15:44:27

Last Modification Time: 21-09-2007 18:34:05

Page number: 6

Laboratory Evaluations

Were the scheduled laboratory samples obtained? YES No, specify

Requisition Number 1 O062471

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 EbZ70229

Patient: J001

Site: CA_001

CRF: Screening

Blank? N

Visit: SCREENING

Visit Date: 21-03-2007

Investigator: C2785_03

CRF Page #: 2

Document #: R139468513



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

CRF Report for Study E6210229

Patient: 001

Site: CA_001

Investigator: C2785_03

CRF: Screening2

Blank? N

CRF Page #: 3

Visit: SCREENING

Visit Date: 21-03-2007

Document #: R139490913

Entered By: Ben Heyen

Entry Time: 25-04-2007 16:21:43

CRF Status: Entry Started

Discrepancies: Closed

Modification Time: 28-11-2007 09:58:20

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Preg_Test

1 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 25-04-2007 17:16:17

Page number: 6

Urine Pregnancy Test

Result

N/A,

MALE

OR

FEMA

LE

Section: Urine_Drug

2 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 25-04-2007 17:16:17

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: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 25-04-2007 17:16:17

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: 21-03-2007

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Screening2

Blank? N

CRF Page #: 3

Visit: SCREENING

Visit Date: 21-03-2007

Document #: R139490913

Section: Med_Hx

4 of 10

Entered By: Ben Heyen

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 25-04-2007 17:16:17

Page number: 7

Medical History

Does the subject have any relevant medical history?

NO

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

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
--------	---------------------	---------------	----------------------------

Section: ECG

5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 25-04-2007 17:16:17

Page number: 8

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

1233

68

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

160

104

408

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: 21-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 27-11-2007 22:15:03

Page number: 9

USUAL BRAND CIGARETTE PACK

DATA

Usual Brand

Type

Length

MARLBORO LIGHTS

NON-MENTHOL

KING SIZE 83-85MM

Style

Pack

How long have these been the subject's usual brand?

LIGHTS/LOW TAR

HARD

UNK

months

UNK

years

Section: Ftc_Tar_Level

7 of 10

Blank? N

Section Status: Created

CRF Report for Study E6270229

Patient: J001

Site: CA_001

Investigator: C2785_03

CRF: Screening2

Blank? N

CRF Page #: 3

Visit: SCREENING

Visit Date: 21-03-2007

Document #: R139490913

Section: Ftc_Tar_Level 7 of 10

Visit: SCREENING

Entered By: Ben Heyen

Section Date: 21-03-2007

Entry Time: 25-04-2007 16:21:43

Last Modification Time:

Page number: 9

FTC TAR LEVEL OF USUAL BRAND

FTC Tar Level (mg)

Section: Expired_Carbon_M 8 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Entered By: Ben Heyen

Section Date: 21-03-2007

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 25-04-2007 17:16:17

Page number: 10

EXPIRED CARBON MONOXIDE

Actual Time

ECO Level (ppm)

%COHb

Comments

1206

14

02.8

Section: Best_Baseline_Sp 9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Entered By: Ben Heyen

Section Date: 21-03-2007

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 07-08-2007 14:50:31

Page number: 10

BEST BASELINE SPIROMETRY TEST RESULT

Actual Time

of FEV1/FVC Test

1211

Testing Position

STANDING

FEV1 L

3.88

FEV 1 Predicted

(%)

85

FVC L

5.15

FVC Predicted

(%)

90

Comments

Section: Ivrs_Training 10 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Entered By: Ben Heyen

Section Date: 21-03-2007

Entry Time: 25-04-2007 16:21:43

Last Modification Time: 25-04-2007 17:16:17

Page number: 10

IVRS TRAINING

Did Subject receive training on the Daily Call-In Diary (IVRS)?

YES

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

CRF Report for Study E6270229

Patient: 001

Site: CA_001

Investigator: C2785_03

CRF: Week-2

Blank? N

CRF Page #: 4

Visit: WEEK -2

Visit Date: 29-03-2007

Document #: R139493513

Entered By: Ben Heyen

Entry Time: 25-04-2007 17:20:50

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 25-04-2007 17:21:36

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Usual_Brand_Coll

Blank? N

Section Status: Entry Complete

Visit: WEEK -2

Section Date: 29-03-2007

Entered By: Ben Heyen

Entry Time: 25-04-2007 17:20:50

Last Modification Time: 25-04-2007 17:21:36

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 EbZ70229

Patient: 001
 CRF: Week 0 Baseline
 Visit: WEEK 0 (BASELINE)

Site: CA_001
 Blank? N
 Visit Date: 15-04-2007
 Entry Time: 13-06-2007 08:53:21
 Modification Time: 29-11-2007 20:55:02
 Approval Time:
 Verification Time:

Investigator: C2785_03
 CRF Page #: 5
 Document #: R145066313
 CRF Status: Entry Complete

Entered By: Ben Heyen
 Discrepancies: None
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Approver:
 Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 15-04-2007	
Entered By: Ben Heyen		Entry Time: 13-06-2007 08:53:21	
		Last Modification Time: 13-06-2007 09:05:02	
		Page number: 12A	

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
15-04-2007		YES

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 15-04-2007	
Entered By: Ben Heyen		Entry Time: 13-06-2007 08:53:21	
		Last Modification Time: 13-06-2007 09:05:02	
		Page number: 12A	

Drug Screen		
Date	Drug Screen Result	
15-04-2007	NEG	

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 15-04-2007	
Entered By: Ben Heyen		Entry Time: 13-06-2007 08:53:21	
		Last Modification Time: 13-06-2007 09:05:02	
		Page number: 12A	

Alcohol Screen		
Date	Breathalyzer Result	
15-04-2007	NEG	

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 15-04-2007	
Entered By: Ben Heyen		Entry Time: 13-06-2007 08:53:21	
		Last Modification Time: 13-06-2007 09:05:02	
		Page number: 12A	

CRF Report for Study EbZ10229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 15-04-2007

Document #: R145066313

Section: Preg_Test 4 of 11

Pregnancy Test

Date

Result

NA

N/A,

MALE

OR

FEMALE

LE

Section: Urine_Coll 5 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 08:53:21

Last Modification Time: 29-11-2007 20:51:06

Page number: 12A

24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	15-04-2007	1526	NA	NA	NA	
0 HOUR TO 24 HOURS	15-04-2007	1526	16-04-2007	1539	2450	

Section: Hdyf_Oral_Health 6 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 08:53:21

Last Modification Time: 13-06-2007 09:05:02

Page number: 13.1

HDYF? INQUIRY

Actual Time

HDYF Performed?

Comments

Date

15-04-2007

1530

YES

Section: Vital 7 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 08:53:21

Last Modification Time: 13-06-2007 09:05:02

Page number: 13.1

VITAL SIGNS

Blood Pressure

Oral

Date

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

15-04-2007

1506

120

80

98

16

ND

NA

CRF Report for Study E6270229

Patient: 001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 15-04-2007

Document #: R145066313

Section: Vital

7 of 11

xxx.x

Comments

Section: Oral_Health_Exam

8 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 08:53:21

Last Modification Time: 29-11-2007 20:55:02

Page number: 13.1

ORAL HEALTH EXAMINATION

Date

15-04-2007

Procedure
ORAL HEALTH QUESTIONS PERFORMED
EVIDENCE OF LEUKOPLAKIA
OTHER ORAL KERATOSIS

Relevant Findings?*
ND
NO
NO

Findings

Section: Phys_Exam

9 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 08:53:21

Last Modification Time: 13-06-2007 09:05:02

Page number: 14.1

PHYSICAL EXAMINATION

Date

15-04-2007

Code Number	Code
01	GENERAL
02	SKIN
03	HEENT
04	MOUTH
05	NECK
06	THORAX/LUNG
07	CARDIO
08	ABDOMEN
09	MUSCULO
10	NEURO
11	LYMPH
12	OTHER

Relevant Findings?
NO
NO
NO
NO
NO
NO
NO
NO
NO
NO
NO
NA

Findings

Section: Weight_Height

10 of 11

Blank? N

Section Status: Entry Complete

CRF Report for Study E6270229

Patient: 001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 15-04-2007

Document #: R145066313

Section: Weight_Height 10 of 11

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 08:53:21

Last Modification Time: 07-08-2007 17:18:50

Page number: 14.1

WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
15-04-2007	98.1	KG	NA	
	xxx.x		xxx.x	

Section: Lab_Eval 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 15-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 08:53:21

Last Modification Time: 08-08-2007 11:36:42

Page number: 15.1

Laboratory Evaluations

Date

15-04-2007

Were the scheduled laboratory samples obtained?

YES

No, specify

Requisition Number 1

N528386

Requisition Number 2 (if applicable)

O062480

Were there any clinically significant labs?

NO

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

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

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145068513

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 11-11-2007 13:56:58

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pk_Blood_Biomark

1 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 15.1

Blood Sampling For Biomarkers/Chemistry/Hematology
(following an overnight fast)

Date	Actual Time	Comments
16-04-2007	0710	

Section: Expired_Carbon_M

2 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 15.1

EXPIRED CARBON MONOXIDE

Date	Actual Time	ECO Level (ppm)	%COHb	Comments
16-04-2007	1551	21	03.9	

Section: Blood_SampL_Cohb

3 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 15.1

Blood Sampling for %COHb

Date	Actual Time	Comments
16-04-2007	1553	

Section: Pre_Bronch_Spir

4 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 07-08-2007 17:35:49

Page number: 16.1

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145068513

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
16-04-2007	1602	STANDI NG	3.92	85	4.85	85	

Section: Proventil_Admin 5 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 16.1

PROVENTIL ADMINISTRATION

Date	Actual Time of Proventil Administration	Amount Administered	Comments
16-04-2007	1619	2 METERED PUFFS	

Section: Post_Bronch_Spir 6 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 16.1

POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT

Date	Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
16-04-2007	1644	STANDING	3.93	86	4.72	82	

Section: Unused_Usual_Bra 7 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 17.1

Unused Usual Brand Cigarette Pack Collection

Date	Does Site have 5 unopened packs of subject's usual brand cigarette to ship to CCLS?	Yes / No
16-04-2007		YES

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145068513

Section: Usual_Brand_Butt 8 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 17.1

Usual Brand Cigarette Butt Collection

Scheduled Collection	Start Date	Start Time	Stop Date	Stop Time	Number of Usual Brand Cigarette Butts Collected	Any Product Deviation?	If yes, number of butts other than usual brand:	Comments
24 HOURS PRIOR TO CHECK-IN	14-04- 2007	1533	15-04-2007	1533	35	NO		
24 HOURS IN-HOUSE	15-04- 2007	1533	16-04-2007	1533	23	NO		

Section: Used_Butt_Measur 9 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 11-11-2007 13:52:56

Page number: 18.1

USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date	Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)
14-04-2007	24 HOURS PRIOR TO CHECK-IN	1	32
		2	40
		3	34
		4	36
		5	33
		6	37
		7	32
		8	31
		9	34
		10	32
		11	38
		12	34
		13	36
		14	35
		15	29
		16	31
		17	30

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145068513

Section: Used_Butt_Measur 9 of 11

18	33
19	33
20	36
21	34
22	37
23	37
24	34
25	33
26	31
27	37
28	34
29	36
30	37
31	32
32	35
33	33
34	30
35	40

Section: Used_Butt_Measur 10 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 11-11-2007 13:56:58

Page number: 19.1

USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date

Period

15-04-2007

24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1	36
2	40
3	41
4	39
5	35
6	40
7	35
8	40
9	36
10	39
11	49

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145068513

Section: Used_Butt_Measur 10 of 11

12	40
13	40
14	41
15	38
16	37
17	38
18	39
19	36
20	39
21	39
22	32
23	36

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:05:08

Last Modification Time: 13-06-2007 09:23:18

Page number: 20.1

RANDOMIZATION

Date	Actual Time	Randomization Sequence
16-04-2007	1654	GROUP B

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

CRF Report for Study E6270229

Patient: J001

Site: CA_001

Investigator: C2785_03

CRF: Week 0 3baseline

Blank? N

CRF Page #: 5.2

Visit: WEEK 0 (BASELINE)

Visit Date: 16-04-2007

Document #: R145071813

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:23:22

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 29-11-2007 20:47:30

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Study_Prod_Dispe

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 13-06-2007 09:23:22

Last Modification Time: 29-11-2007 20:47:30

Page number: 23.1

STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
16-04-2007	UNK	SNUS	FROST	60

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

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Intercurrent_III

Blank? N

CRF Page #: 7

Visit: INTERCURRENT ILL

Visit Date: 16-04-2007

Document #: R165921613

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:05:45

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 11-11-2007 14:06:17

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Ip_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:05:45

Last Modification Time: 11-11-2007 14:06:17

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		Resolved / Changed		Severity	Relationship to Procedure	Action Taken
			Date	Time	Date	Time			

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 1

Blank? Y

CRF Page #: 8

Visit: WEEK 1

Visit Date: 16-04-2007

Document #: R165921913

Entered By: Ben Heven

Entry Time: 11-11-2007 14:09:29

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Hdyf_Oral_Health

1 of 5

Blank? Y

Section Status: Created

Visit: WEEK 1

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:09:29

Last Modification Time:

Page number: 22

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Oral Health

Questions

Actual Time

HDYF Performed?

Performed?

Comments

Section: Vital

2 of 5

Blank? Y

Section Status: Created

Visit: WEEK 1

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:09:29

Last Modification Time:

Page number: 22

VITAL SIGNS

Blood Pressure

Oral

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Expired_Carbon_M

3 of 5

Blank? Y

Section Status: Created

Visit: WEEK 1

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:09:29

Last Modification Time:

Page number: 22

EXPIRED CARBON MONOXIDE

Actual Time

ECO Level (ppm)

%COHb

Comments

Section: Unused_Study_Pro

4 of 5

Blank? Y

Section Status: Created

Visit: WEEK 1

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:09:29

Last Modification Time:

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Week 1

Blank? Y

CRF Page #: 8

Visit: WEEK 1

Visit Date: 16-04-2007

Document #: R165921913

Section: Unused_Study_Pro

4 of 5

Page number: 23

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 1

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:29

Last Modification Time:

Page number: 23

STUDY PRODUCT DISPENSATION

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

CRF Report for Study Eb270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Week 2

Blank? Y

CRF Page #: 9

Visit: WEEK 2

Visit Date: 16-04-2007

Document #: R165922013

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:38

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Hdyf_Oral_Health

1 of 6

Blank? Y

Section Status: Created

Visit: WEEK 2

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:38

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:38

Last Modification Time:

Page number: 24

VITAL SIGNS

Blood Pressure

Oral

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Expired_Carbon_M

3 of 6

Blank? Y

Section Status: Created

Visit: WEEK 2

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:38

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:38

Last Modification Time:

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Week 2

Blank? Y

CRF Page #: 9

Visit: WEEK 2

Visit Date: 16-04-2007

Document #: R165922013

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:38

Last Modification Time:

Page number: 25

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 2

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:38

Last Modification Time:

Page number: 25

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 4

Blank? Y

CRF Page #: 10

Visit: WEEK 4

Visit Date: 16-04-2007

Document #: R165922113

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:45

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pro_Questionnaire

1 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:45

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: HDYF_Oral_Health

2 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:45

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:45

Last Modification Time:

Page number: 26

VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
	Systolic	Diastolic			Temperature	
					xxx.x	

Comments

Section: Expired_Carbon_M

4 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 16-04-2007

CRF Report for Study E6270229

Patient: 5001
CRF: Week 4
Visit: WEEK 4

Site: CA_001
Blank? Y
Visit Date: 16-04-2007

Investigator: C2785_03
CRF Page #: 10
Document #: R165922113

Section: Expired_Carbon_M 4 of 6

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:45

Last Modification Time:

Page number: 26

EXPIRED CARBON MONOXIDE

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

Section: Unused_Study_Pro

5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:45

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:45

Last Modification Time:

Page number: 27

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 6

Blank? Y

CRF Page #: 11

Visit: WEEK 6

Visit Date: 16-04-2007

Document #: R165922213

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:52

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Verifier:

Approval Status: Not Approved

Approval Time:

Verification: Not Verified

Verification Time:

Comment:

Section: Hdyf_Oral_Health

1 of 5

Blank? Y

Section Status: Created

Visit: WEEK 6

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:52

Last Modification Time:

Page number: 28

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Oral Health
Questions
Performed?

Actual Time

HDYF Performed?

Comments

Section: Expired_Carbon_M

2 of 5

Blank? Y

Section Status: Created

Visit: WEEK 6

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:52

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:52

Last Modification Time:

Page number: 28

VITAL SIGNS

Blood Pressure

Oral

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Unused_Study_Pro

4 of 5

Blank? Y

Section Status: Created

Visit: WEEK 6

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:52

Last Modification Time:

CRF Report for Study Eb270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 6

Blank? Y

CRF Page #: 11

Visit: WEEK 6

Visit Date: 16-04-2007

Document #: R165922213

Section: Unused_Study_Pro

4 of 5

Page number: 29

Unused Study Product Returned

Amount Returned

Product Returned

Flavor

Packs

Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 6

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:52

Last Modification Time:

Page number: 29

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study Eb270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 8

Blank? Y

CRF Page #: 13

Visit: WEEK 8

Visit Date: 16-04-2007

Document #: R165922313

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:58

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pro_Questionnair

1 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:58

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:58

Last Modification Time:

Page number: 30

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Oral Health
Questions
Performed?

Actual Time

HDYF Performed?

Comments

Section: Vital

3 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:58

Last Modification Time:

Page number: 30

VITAL SIGNS

Blood Pressure

Oral

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Expired_Carbon_M

4 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 16-04-2007

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 8

Blank? Y

CRF Page #: 13

Visit: WEEK 8

Visit Date: 16-04-2007

Document #: R165922313

Section: Expired_Carbon_M

4 of 6

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:58

Last Modification Time:

Page number: 30

EXPIRED CARBON MONOXIDE

Actual Time

ECO Level (ppm)

%COHb

Comments

Section: Unused_Study_Pro

5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:58

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:09:58

Last Modification Time:

Page number: 31

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 10

Blank? Y

CRF Page #: 14

Visit: WEEK 10

Visit Date: 16-04-2007

Document #: R165922413

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:05

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Hdyf_Oral_Health

1 of 5

Blank? Y

Section Status: Created

Visit: WEEK 10

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:05

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:05

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:05

Last Modification Time:

Page number: 32

VITAL SIGNS

Blood Pressure

Oral

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Unused_Study_Pro

4 of 5

Blank? Y

Section Status: Created

Visit: WEEK 10

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:05

Last Modification Time:

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 10

Blank? Y

CRF Page #: 14

Visit: WEEK 10

Visit Date: 16-04-2007

Document #: R165922413

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:05

Last Modification Time:

Page number: 33

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 12

Blank? Y

CRF Page #: 15

Visit: WEEK 12

Visit Date: 16-04-2007

Document #: R165922513

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pro_Questionnair

1 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

Last Modification Time:

Page number: 34

Pregnancy Test

CRF Report for Study EbZ70229

Patient: 0001
CRF: Week 12
Visit: WEEK 12

Site: CA_001
Blank? Y
Visit Date: 16-04-2007

Investigator: C2785_03
CRF Page #: 15
Document #: R165922513

Section: Preg_Test 4 of 11

Date Result

Section: Urine_Coll 5 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

Last Modification Time:

Page number: 35

VITAL SIGNS

Blood Pressure

Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature xxx.x	Unit
------	-------------	----------	-----------	-------	------------------	---------------------------	------

Comments

Section: Oral_Health_Exam 8 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

Last Modification Time:

Page number: 35

ORAL HEALTH EXAMINATION

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 12

Blank? Y

CRF Page #: 15

Visit: WEEK 12

Visit Date: 16-04-2007

Document #: R165922513

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

Last Modification Time:

Page number: 36

WEIGHT & HEIGHT

Date

Weight

Unit

Height

Unit

xxx.x

xxx.x

Section: Lab_Eval

11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:12

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: 001

Site: CA_001

Investigator: C2785_03

CRF: Week 12(2)

Blank? Y

CRF Page #: 16

Visit: WEEK 12

Visit Date: 16-04-2007

Document #: R165922613

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:21

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:21	
		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: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:21	
		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: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:21	
		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: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:21	
		Last Modification Time:	
		Page number: 38	

PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT

Actual Time

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 12(2)

Blank? Y

CRF Page #: 16

Visit: WEEK 12

Visit Date: 16-04-2007

Document #: R165922613

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:21

Last Modification Time:

Page number: 38

PROVENTIL ADMINISTRATION

Actual Time

of Proventil

Date	Administration	Amount Administered	Comments
------	----------------	---------------------	----------

Section: Post_Bronch_Spir 6 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:21

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:21

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:21

CRF Report for Study E6270229

Patient: 3001
 CRF: Week 12(2)
 Visit: WEEK 12

Site: CA_001
 Blank? Y
 Visit Date: 16-04-2007

Investigator: C2785_03
 CRF Page #: 16
 Document #: R165922613

Section: Used_Study_Snus 8 of 11

Last Modification Time:
 Page number: 40

USED STUDY SNUS COLLECTION

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

Section: Used_Study_Burn 9 of 11 Blank? Y Section Status: Created
 Visit: WEEK 12 Section Date: 16-04-2007
 Entered By: Ben Heyen Entry Time: 11-11-2007 14:10:21
 Last Modification Time:
 Page number: 41

USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used_Butt_Measur 10 of 11 Blank? Y Section Status: Created
 Visit: WEEK 12 Section Date: 16-04-2007
 Entered By: Ben Heyen Entry Time: 11-11-2007 14:10:21
 Last Modification Time:
 Page number: 42

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

Section: Used_Butt_Measur 11 of 11 Blank? Y Section Status: Created
 Visit: WEEK 12 Section Date: 16-04-2007
 Entered By: Ben Heyen Entry Time: 11-11-2007 14:10:21
 Last Modification Time:
 Page number: 43

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 12(3)

Blank? Y

CRF Page #: 17

Visit: WEEK 12

Visit Date: 16-04-2007

Document #: R165922713

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:30

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Unused_Study_Pro

1 of 2

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:30

Last Modification Time:

Page number: 44

Unused Study Product Returned

Amount Returned

Date	Actual Time	Product Returned	Flavor	Packs	Individual Cigarettes / pouches
------	-------------	------------------	--------	-------	---------------------------------

Section: Study_Prod_Dispe

2 of 2

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:30

Last Modification Time:

Page number: 44

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Week 14

Blank? Y

CRF Page #: 18

Visit: WEEK 14

Visit Date: 16-04-2007

Document #: R165922813

Entered By: Ben Heven

Entry Time: 11-11-2007 14:10:37

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Hdyf_Oral_Health

1 of 5

Blank? Y

Section Status: Created

Visit: WEEK 14

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:10:37

Last Modification Time:

Page number: 45

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

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

Section: Expired_Carbon_M

2 of 5

Blank? Y

Section Status: Created

Visit: WEEK 14

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:10:37

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: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:10:37

Last Modification Time:

Page number: 45

VITAL SIGNS

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

Section: Unused_Study_Pro

4 of 5

Blank? Y

Section Status: Created

Visit: WEEK 14

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:10:37

Last Modification Time:

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 14

Blank? Y

CRF Page #: 18

Visit: WEEK 14

Visit Date: 16-04-2007

Document #: R165922813

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:37

Last Modification Time:

Page number: 46

STUDY PRODUCT DISPENSATION

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

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 16

Blank? Y

CRF Page #: 19

Visit: WEEK 16

Visit Date: 16-04-2007

Document #: R165922913

Entered By: Ben Heven

Entry Time: 11-11-2007 14:10:43

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pro_Questionnair 1 of 6 Blank? Y
 Visit: WEEK 16 Section Date: 16-04-2007
 Entered By: Ben Heven Entry Time: 11-11-2007 14:10:43
 Last Modification Time:
 Page number: 47

Section Status: Created

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
 Visit: WEEK 16 Section Date: 16-04-2007
 Entered By: Ben Heven Entry Time: 11-11-2007 14:10:43
 Last Modification Time:
 Page number: 47

Section Status: Created

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments

Section: Vital 3 of 6 Blank? Y
 Visit: WEEK 16 Section Date: 16-04-2007
 Entered By: Ben Heven Entry Time: 11-11-2007 14:10:43
 Last Modification Time:
 Page number: 47

Section Status: Created

VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
	Systolic	Diastolic			Temperature xxx.x	

Comments

Section: Expired_Carbon_M 4 of 6 Blank? Y
 Visit: WEEK 16 Section Date: 16-04-2007

Section Status: Created

CRF Report for Study E6270229

Patient: 5001
CRF: Week 16
Visit: WEEK 16

Site: CA_001
Blank? Y
Visit Date: 16-04-2007

Investigator: C2785_03
CRF Page #: 19
Document #: R165922913

Section: Expired_Carbon_M 4 of 6

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:43

Last Modification Time:

Page number: 47

EXPIRED CARBON MONOXIDE

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

Section: Unused_Study_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:43

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:43

Last Modification Time:

Page number: 48

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 18

Blank? Y

CRF Page #: 20

Visit: WEEK 18

Visit Date: 16-04-2007

Document #: R165923013

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:50

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:50	
		Last Modification Time:	
		Page number: 49	

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Oral Health
Questions
Performed?

Actual Time	HDYF Performed?	Comments
-------------	-----------------	----------

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:50	
		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: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:50	
		Last Modification Time:	
		Page number: 49	

VITAL SIGNS

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

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:10:50	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Week 18

Blank? Y

CRF Page #: 20

Visit: WEEK 18

Visit Date: 16-04-2007

Document #: R165923013

Section: Unused_Study_Pro 4 of 5

Page number: 50

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 18

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:50

Last Modification Time:

Page number: 50

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 20

Blank? Y

CRF Page #: 21

Visit: WEEK 20

Visit Date: 16-04-2007

Document #: R165923113

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:57

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pro_Questionnair

1 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:57

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: Hdy_Oral_Health

2 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:57

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:57

Last Modification Time:

Page number: 51

VITAL SIGNS

Blood Pressure

Oral

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Expired_Carbon_M

4 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 16-04-2007

CRF Report for Study E6270229

Patient: 5001
CRF: Week 20
Visit: WEEK 20

Site: CA_001
Blank? Y
Visit Date: 16-04-2007

Investigator: C2785_03
CRF Page #: 21
Document #: R165923113

Section: Expired_Carbon_M 4 of 6

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:57

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:57

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:10:57

Last Modification Time:

Page number: 52

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Week 22

Blank? Y

CRF Page #: 22

Visit: WEEK 22

Visit Date: 16-04-2007

Document #: R165923213

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:04

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:04	
		Last Modification Time:	
		Page number: 53	

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:04	
		Last Modification Time:	
		Page number: 53	

EXPIRED CARBON MONOXIDE

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

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:04	
		Last Modification Time:	
		Page number: 53	

VITAL SIGNS

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

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:04	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 22

Blank? Y

CRF Page #: 22

Visit: WEEK 22

Visit Date: 16-04-2007

Document #: R165923213

Section: Unused_Study_Pro

4 of 5

Page number: 54

Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe

5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 22

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:04

Last Modification Time:

Page number: 54

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229

Patient: 001

Site: CA_001

Investigator: C2785_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923313

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pro_Questionnair	1 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:13	
		Last Modification Time:	
		Page number: 55	

PRO QUESTIONNAIRES

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

Section: Urine_Drug	2 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:13	
		Last Modification Time:	
		Page number: 55	

Drug Screen

Date	Drug Screen Result
------	--------------------

Section: Alcohol_Screen	3 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:13	
		Last Modification Time:	
		Page number: 55	

Alcohol Screen

Date	Breathalyzer Result
------	---------------------

Section: Preg_Test	4 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 16-04-2007	
Entered By: Ben Heyen		Entry Time: 11-11-2007 14:11:13	
		Last Modification Time:	
		Page number: 55	

Pregnancy Test

CRF Report for Study E6270229

Patient: J001

Site: CA_001

Investigator: C2785_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923313

Section: Preg_Test 4 of 12

Date Result

Section: Urine_Coll 5 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

Last Modification Time:

Page number: 55

24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
---------------------	------------	------------	-----------	-----------	--------------	----------

Section: ECG 6 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

Last Modification Time:

Page number: 56

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time Ventricular Heart Rate

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

ECG INTERPRETATION:

Comments (related to abnormal, CS findings only):

Section: Hdyf_Oral_Health 7 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

Last Modification Time:

Page number: 57

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

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

Section: Vital 8 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

Last Modification Time:

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923313

Section: Vital

8 of 12

Page number: 57

VITAL SIGNS

Blood Pressure

Oral

Date

Actual Time

Systolic

Diastolic

Pulse

Respiratory Rate

Temperature

Unit

xxx.x

Comments

Section: Oral_Health_Exam

9 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

Last Modification Time:

Page number: 57

ORAL HEALTH EXAMINATION

Date

Procedure

Relevant Findings?*

Findings

Section: Phys_Exam

10 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

Last Modification Time:

Page number: 58

PHYSICAL EXAMINATION

Date

Code Number

Code

Relevant Findings?

Findings

Section: Weight_Height

11 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

Last Modification Time:

Page number: 58

WEIGHT & HEIGHT

Date

Weight

Unit

Height

Unit

xxx.x

xxx.x

Section: Lab_Eval

12 of 12

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:11:13

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 24 (Eos)

Blank? Y

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923313

Section: Lab_Eval

12 of 12

Last Modification Time:

Page number: 59

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

No, specify

Requisition Number 1

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

CRF Report for Study Eb270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 24-2 (Eos)

Blank? Y

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923413

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:02

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pk_Blood_Biomark

1 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 59

Blood Sampling For Biomarkers/Chemistry/Hematology
(following an overnight fast)

Date

Actual Time

Comments

Section: Expired_Carbon_M

2 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 59

EXPIRED CARBON MONOXIDE

Date

Actual Time

ECO Level (ppm)

%COHb

Comments

Section: Blood_Sampl_Cohb

3 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 59

Blood Sampling for %COHb

Date

Actual Time

Comments

Section: Pre_Bronch_Spir

4 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 60

PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT

Actual Time

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Week 24-2 (Eos)

Blank? Y

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923413

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 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 60

PROVENTIL ADMINISTRATION

Actual Time

of Proventil

Date	Administration	Amount Administered	Comments
------	----------------	---------------------	----------

Section: Post_Bronch_Spir

6 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 60

POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT

Actual Time

of FEV1/FVC

Date	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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 61

USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION

Number of Study
Tobacco-Heating

Weight of

Scheduled Collection Timepoint	Start Date	Start Time	Stop Date	Stop Time	Cigarettes Collected	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 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:02

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Week 24-2 (Eos)

Blank? Y

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923413

Section: Used_Study_Snus

8 of 11

Last Modification Time:

Page number: 62

USED STUDY SNUS COLLECTION

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

Section: Used_Study_Burn

9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:02

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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 64

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date	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: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:02

Last Modification Time:

Page number: 65

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection

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

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Week 24-3

Blank? Y

CRF Page #: 25

Visit: WEEK 24 (EOS)

Visit Date: 16-04-2007

Document #: R165923513

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:11

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Unused_Study_Pro

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:11

Last Modification Time:

Page number: 65A

Unused Study Product Returned

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

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Precon_Med

Blank? N

CRF Page #: 26

Visit: PRECON_MEDS

Visit Date: 16-04-2007

Document #: R165923613

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:17

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 29-11-2007 21:00:06

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pre_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON_MEDS

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:17

Last Modification Time: 29-11-2007 21:00:06

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?

NO

Seq #	Drug Name	Indication	Dose / Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing
-------	-----------	------------	---------------------	-------	---------	------	---------	------------	-------------------

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: AE

Blank? N

CRF Page #: 27

Visit: AE

Visit Date: 16-04-2007

Document #: R165923713

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:23

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 29-11-2007 21:00:21

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Ae_Med

Blank? N

Section Status: Entry Complete

Visit: AE

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:23

Last Modification Time: 29-11-2007 21:00:21

Page number: 67

Adverse Events

Did the subject experience any adverse events?

NO

Event No.	Adverse Event	Onset		Resolved/Changed		Serious Event?	Severity	Relationship to Product	Relationship to Procedure	Action Taken	Outcome to Date
		Date	Time	Date	Time						

CRF Report for Study E6270229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Ecg_Unscheduled

Blank? Y

CRF Page #: 28

Visit: ECG_UNSCHE

Visit Date: 16-04-2007

Document #: R165923813

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:31

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: ECG

Blank? Y

Section Status: Created

Visit: ECG_UNSCHE

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:31

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: 0001

Site: CA_001

Investigator: C2785_03

CRF: Lab_Unscheduled

Blank? Y

CRF Page #: 29

Visit: LAB_UNSCHE

Visit Date: 16-04-2007

Document #: R165923913

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:37

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Lab_Eval

Blank? Y

Section Status: Created

Visit: LAB_UNSCHE

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:37

Last Modification Time:

Page number: 69

Unscheduled Laboratory Evaluations

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

CRF Report for Study E6210229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Vital_Unscheduled

Blank? Y

CRF Page #: 30

Visit: VITAL_UNSCHE

Visit Date: 16-04-2007

Document #: R165924013

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:46

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL_UNSCHE

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:12:46

Last Modification Time:

Page number: 70

UNSCHEDULED VITAL SIGNS

Date	Actual Time	Blood Pressure		Pulse	Respiratory	Oral	Unit	Comments
		Systolic	Diastolic		Rate	Temperature		

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Stdy_Prdt_Dis_Unscheduled

Blank? Y

CRF Page #: 31

Visit: STDY_PRDT_UNSCHE

Visit Date: 16-04-2007

Document #: R165924113

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:57

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Study_Prod_Dispe

Blank? Y

Section Status: Created

Visit: STDY_PRDT_UNSCHE

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:12:57

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: 3001

Site: CA_001

Investigator: C2785_03

CRF: Expired_Co2_Unscheduled

Blank? Y

CRF Page #: 32

Visit: EXPIRED_CO2_UNSC

Visit Date: 16-04-2007

Document #: R165924313

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:13:22

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Expired_Carbon_M

Blank? Y

Section Status: Created

Visit: EXPIRED_CO2_UNSC

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:13:22

Last Modification Time:

Page number: 72

UNSCHEDULED EXPIRED CARBON MONOXIDE

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

CRF Report for Study E6270229

Patient: 3001

Site: CA_001

Investigator: C2785_03

CRF: Oral_Health_Unscheduled

Blank? Y

CRF Page #: 33

Visit: ORAL_HEALTH_UNSC

Visit Date: 16-04-2007

Document #: R165924413

Entered By: Ben Heven

Entry Time: 11-11-2007 14:13:27

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Oral_Health_Exam

Blank? Y

Section Status: Created

Visit: ORAL_HEALTH_UNSC

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:13:27

Last Modification Time:

Page number: 73

UNSCHEDULED ORAL HEALTH EXAMINATION

Date	Actual Time	Code	Relevant Findings?	Comment
------	-------------	------	--------------------	---------

CRF Report for Study E6270229

Patient: 0001

Site: CA_001

Investigator: C2785_03

CRF: Spirometry_Unscheduled

Blank? Y

CRF Page #: 34

Visit: SPIRO_TEST_UNSCH

Visit Date: 16-04-2007

Document #: R165924513

Entered By: Ben Heven

Entry Time: 11-11-2007 14:13:37

CRF Status: Created

Discrepancies: None

Modification Time:

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Pre_Bronch_Spir

Blank? Y

Section Status: Created

Visit: SPIRO_TEST_UNSCH

Section Date: 16-04-2007

Entered By: Ben Heven

Entry Time: 11-11-2007 14:13:37

Last Modification Time:

Page number: 74

UNSCHEDULED SPIROMETRY TEST RESULT

Proventil

Administration

FEV1

FVC

Actual Time

Timepoint based

(and time of

Predicted

Predicted

Date

of FEV1/FVC

Testing

on Proventil

Administration)

(Time)

FEV1 L

(%)

FVC L

(%)

Comments

Test

Position

Administration

Administration)

(Time)

FEV1 L

(%)

FVC L

(%)

Comments

CRF Report for Study E6210229

Patient: 5001

Site: CA_001

Investigator: C2785_03

CRF: Study_Completion

Blank? N

CRF Page #: 35

Visit: STUDY_COMP

Visit Date: 16-04-2007

Document #: R165924613

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:13:43

CRF Status: Entry Complete

Discrepancies: Active

Modification Time: 28-11-2007 09:58:20

Approver:

Approval Status: Not Approved

Approval Time:

Verifier:

Verification: Not Verified

Verification Time:

Comment:

Section: Study_Comp

Blank? N

Section Status: Entry Complete

Visit: STUDY_COMP

Section Date: 16-04-2007

Entered By: Ben Heyen

Entry Time: 11-11-2007 14:13:43

Last Modification Time: 27-11-2007 22:18:15

Page number: 75

Study Completion

Did the subject complete the study?

NO

Date the subject completed OR withdrew from the study:

16-04-2007

Reason for Withdrawal

CONSENT

Specify

SUBJECT DID NOT WANT TO CONTINUE USE OF SNUS PRODUCTS

Investigator Comments

Principal Investigator

Date

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

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

Elanor MD
30 Nov 2007

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. 0062471

Page 1 of 3

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:41 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No


CHEMISTRY PANEL

Total Bili	1.3	H	0.2-1.2 mg/dL
Alk Phos	99		31-129 U/L
ALT (SGPT)	19		6-43 U/L
AST (SGOT)	15		11-36 U/L
GGT	38		10-61 U/L
LDH	122		53-234 U/L
Urea Nitr	16		4-24 mg/dL
Creatinine	1.1		0.5-1.2 mg/dL
Glucose	90		70-115 mg/dL
Uric Acid	6.8		2.1-8.2 mg/dL
Calcium	9.9		8.3-10.6 mg/dL
Phosphorus	4.2		2.2-5.1 mg/dL
Total Prot	7.8		6.1-8.4 g/dL
Albumin	4.6		3.3-4.9 g/dL
Sodium	143		132-147 mEq/L
Potassium	5.0		3.4-5.4 mEq/L
Chloride	103		94-112 mEq/L

[]

[x]

100% QC
Ans 28 MAR 07

Investigator Signature: 3.23.07
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

B17181

(INV)

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SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

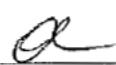
Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	16.4	12.7-18.1 g/dL
HCT	50	39-54 %
RBC	5.3	4.5-6.4x10 ⁶ /uL
MCV	94	79-96 fL
MCH	31	26-34 pg
MCHC	33	31-38 g/dL
RDW	14.4	12.0-15.0 %
RBC Morph	Normocytic	
WBC	4.14	3.80-10.70 x10 ³ /uL
Neutrophil	2.63	1.96-7.23 x10 ³ /uL
Lymphocyte	1.13	0.91-4.28 x10 ³ /uL
Monocytes	0.28	0.12-0.92 x10 ³ /uL
Eosinophil	0.06	0.00-0.57 x10 ³ /uL
Basophils	0.02	0.00-0.20 x10 ³ /uL
Neutrophil	63.7	40.5-75.0 %
Lymphocyte	27.4	15.4-48.5 %
Monocytes	6.9	2.6-10.1 %
Eosinophil	1.5	0.0-6.8 %
Basophils	0.5	0.0-2.0 %
Platelets	229	140-400 x10 ³ /uL

100% QC
Aus 28 MAR 07


Investigator Signature:

3.23.07
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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Madison, WI United States 53704

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DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

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	1.025	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
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

MISCELLANEOUS ELEMENTS

Mucous Present Ref Rng: Not present

10076 QC
Ans 28 MAR 07


Investigator Signature:

3.23.07
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:41 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 105 45-160 ug/dL

HEPATITIS A ANTIBODY-IGM

HepA IgM Ab Negative No Ref Rng

100% QC
Aus 28 MAR 07



Investigator Signature:

3.23.07

Date:

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

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INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

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DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B SURFACE ANTIGEN

HBSAG

Negative

No Ref Rng

HEPATITIS C VIRUS ANTIBODY

ANTI-HCV

Negative

No Ref Rng

HEPATITIS B SURFACE ANTIBODY

HBSAB

Negative

No Ref Rng

100% QC
Aus 28 MAR 07



Investigator Signature:

3.23.07

Date:

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

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:41 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

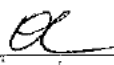
HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive

100% QC
Aus 28 MAR 07


Investigator Signature:

3-23-07
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 Y=Telephoned P="Panic" EX=Exclusions as specified by the Sponsor

B17181

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

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DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

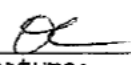
Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng:Negative

100% QC
Aus 28 MAR 07


Investigator Signature:

3-23-07
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

B17181

(INV)

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. 0062471

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME:12:41 DATE:21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

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

100% QC
Aus 28 MAR 07



Investigator Signature:

3.23.07

Date:

B17181

(INV)

Covance CLS

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8211 SciCor Drive - Indianapolis, IN 46214-2985
Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	1.8	H	0.2-1.2 mg/dL
Alk Phos	88		31-129 U/L
ALT (SGPT)	22		6-43 U/L
AST (SGOT)	21		11-36 U/L
GGT	43		10-61 U/L
LDH	147		53-234 U/L
Urea Nitr	15		4-24 mg/dL
Creatinine	1.1		0.5-1.2 mg/dL
Glucose	92		70-115 mg/dL
Uric Acid	5.7		2.1-8.2 mg/dL
Calcium	9.3		8.3-10.6 mg/dL
Phosphorus	3.7		2.2-5.1 mg/dL
Total Prot	6.5		6.1-8.4 g/dL
Albumin	4.0		3.3-4.9 g/dL
Sodium	140		132-147 mEq/L
Potassium	4.0		3.4-5.4 mEq/L
Chloride	104		94-112 mEq/L

[]

[x] UB

Linda Bardoel msn/FAP 11 Jun 07
Investigator Signature:

04/23/07
Date:

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B17181

(INV)

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Austin, TX 78752

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.: 5
RANDOMIZATION NUMBER: R5001
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007
DATE RECEIVED IN LABORATORY: 16-Apr-2007
DATE REPORTED BY LABORATORY: 20-Apr-2007
SEX: M BIRTHDATE: (b) (6) AGE: 36
SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CARBOXYHEMOGLOBIN

Carboxyhem 5.1

% saturation
No Ref Rng

VCP

Linda Cardoza
Investigator Signature:

11 Jun 07

04/23/07
Date:

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B17181

(INV)

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LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

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c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HOMOCYSTEINE

*1 HCY

12.40

5.90-16.00 umol/L

JLB

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.

Linda Bardo
Investigator Signature:

OR 11 Jun 07

04/23/07
Date:

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B17181

(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

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c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

SPONSOR REPORT TO:

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

PROTOCOL 5270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	15.8	12.7-18.1 g/dL
HCT	49	39-54 %
RBC	5.2	4.5-6.4x10 ⁶ /uL
MCV	95	79-96 fL
MCH	31	26-34 pg
MCHC	32	31-38 g/dL
RDW	14.2	12.0-15.0 %
RBC Morph	Normocytic	
WBC	5.16	3.80-10.70 x10 ³ /uL
Neutrophil	3.07	1.96-7.23 x10 ³ /uL
Lymphocyte	1.60	0.91-4.28 x10 ³ /uL
Monocytes	0.36	0.12-0.92 x10 ³ /uL
Eosinophil	0.09	0.00-0.57 x10 ³ /uL
Basophils	0.03	0.00-0.20 x10 ³ /uL
Neutrophil	59.6	40.5-75.0 %
Lymphocyte	31.2	15.4-48.5 %
Monocytes	7.0	2.6-10.1 %
Eosinophil	1.7	0.0-6.8 %
Basophils	0.6	0.0-2.0 %
Platelets	231	140-400 x10 ³ /uL

Investigator Signature: 

Date: 19 Apr 07

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Madison, WI United States 53704

PROTOCOL 6270-229
INVESTIGATOR NO.: 5
RANDOMIZATION NUMBER: R5001
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0


COLLECTION TIME: 15:26 DATE: 15-Apr-2007
DATE RECEIVED IN LABORATORY: 16-Apr-2007
DATE REPORTED BY LABORATORY: 19-Apr-2007
SEX: M BIRTHDATE: (b) (6) AGE: 36
SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes No

C-REACTIVE PROTEIN

CRP-HS 0.173 <=0.287 mg/dL


Investigator Signature:

19 Apr 07
Date:

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INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

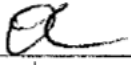
Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store

Completed


Investigator Signature:

19 Apr 07
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c


4.9

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%


Investigator Signature:

19 Apr 07
Date:

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LABORATORY REPORT

ACCESSION NO. 0062480

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INVESTIGATOR: (B17181)

David Carter, M.D.

c/o Marianna Alesi

Covance-Austin

313 East Anderson Lane #200

Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 19-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

LIPID PANEL

Triglycer	107	50-321 mg/dL
Cholest	184	150-264 mg/dL
HDL Dex-S	60	29-62 mg/dL
LDL Chol	103	81-189 mg/dL


Investigator Signature:

19 Apr 07
Date:

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

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(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

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.: 5
RANDOMIZATION NUMBER: R5001
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0


COLLECTION TIME: 15:26 DATE: 15-Apr-2007
DATE RECEIVED IN LABORATORY: 16-Apr-2007
DATE REPORTED BY LABORATORY: 18-Apr-2007
SEX: M BIRTHDATE: (b) (6) AGE: 36
SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes No

FIBRINOGEN

Fibrinogen 247 200-400 mg/dL


Investigator Signature:

19 Apr 07
Date:

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B17181

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Austin, TX 78752

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?


Yes

No

FIBRINOGEN - See Note #1

Fibrinogen Awaiting specimen arrival

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


Investigator Signature:

11 June 07
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

B17181

(INW)

Covance CLS

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LABORATORY REPORT

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Page 1 of 1

INVESTIGATOR: (B17181)

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c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes No

sICAM-1 - See Note #1

sICAM-1 Awaiting specimen arrival

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


Investigator Signature:

11 Jun 07
Date:

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B17181

(INV)

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LABORATORY REPORT

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INVESTIGATOR: (B17181)

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c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME:15:26 DATE:15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

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

Note #1 - No specimen received


Investigator Signature:11 Jun 07
Date:

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B17181

(INV)

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?


Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes


Investigator Signature:

11 Jun 07
Date:

817181

(INV)

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

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229**INVESTIGATOR NO.: 5****RANDOMIZATION NUMBER:****PATIENT INITIALS: (b) (6)****VISIT: 2****SPONSOR REPORT TO:**

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

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMOGLOBIN A1C - See Note #1

Note #1 - No specimen received


Investigator Signature:

11 Jun 07
Date:

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B17181

(INV)

Covance CLS

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LABORATORY REPORT

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Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME:15:26 DATE:15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

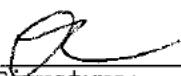
Is this Clinically
Significant/ Adverse
Event?

Yes

No

LIPID PANEL - See Note #1

Note #1 - No specimen received


Investigator Signature:21 Jun 07
Date:

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B17181

(INV)

Covance CLS

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

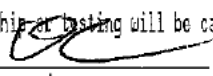
Yes

No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

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

Investigator Signature: 11 Jun 07
Date:

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

B17181

(INV)

LOCATION: Covance CLS

RX TIME 04/17 '07 00:03

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

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.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

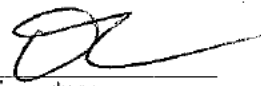
No

TOTAL IRON - See Note #1

C-REACTIVE PROTEIN - See Note #1

CARBOXYHEMOGLOBIN - See Note #1

Note #1 - No specimen received


Investigator Signature:11 Jun 07
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

B17181

(INV)

Covance CLS

Marietta Henry, M.D., Director
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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 16-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

HOMOCYSTEINE - See Note #1

Note #1 - No specimen received


Investigator Signature:11 Jun 07
Date:

H(High) or L(Low): Values above or below Covance CLS reference range

B17181

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

(INV)

LOCATION: Covance CLS

Covance CLS
RX TIME 04/16 '07 23:57

Covance CLS

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

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 17-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes

No

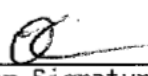
CHEMISTRY PANEL - See Note #1

HEMATOLOGY& DIFFERENTIAL PANEL - See Note #1

URINE MACRO & MICRO PANEL

Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.008	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
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Negative	

Note #1 - No specimen received

Investigator Signature: 18 Apr 07
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

B17181

(INV)

Covance CLS

Marietta Henry, M.D., Director
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Tel. #1 (800) 327 7270
LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229
INVESTIGATOR NO.: 5
RANDOMIZATION NUMBER:
PATIENT INITIALS: (b) (6)
VISIT: 2

SPONSOR REPORT TO:

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

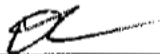
Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007
DATE RECEIVED IN LABORATORY: 16-Apr-2007
DATE REPORTED BY LABORATORY: 17-Apr-2007
SEX: M BIRTHDATE: (b) (6) AGE: 36
SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?
Yes No

URINE CREATININE, SPOT
Rnd Ur Crt 55

mg/dL No Ref Rng


Investigator Signature:

18 Apr 07
Date:

H(High) or L(Low)-Values above or below Covance CLS reference range
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B17181

(INV)

Covance CLS

Marietta Henry, M.D., Director
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LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5001

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 21-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011


Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 140 45-160 ug/dL


Investigator Signature:

28 Apr 07
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

B17181

(INV)

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. 0062480

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
c/o Marianna Alesi
Covance-Austin
313 East Anderson Lane #200
Austin, TX 78752

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.: 5
RANDOMIZATION NUMBER: R5001
PATIENT INITIALS: (b) (6)
VISIT: 2

Week 0

COLLECTION TIME: 15:26 DATE: 15-Apr-2007

DATE RECEIVED IN LABORATORY: 16-Apr-2007

DATE REPORTED BY LABORATORY: 27-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 36

SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?


Yes No

sICAM-1

sICAM-1

245

115-306 ng/mL


Investigator Signature:

03 May 07
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

B17181

(INV)

Covance CLS

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8211 SciCor Drive - Indianapolis, IN 46214-2985
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LABORATORY REPORT

ACCESSION NO. N528386

Page 1 of 1

INVESTIGATOR: (B17181)

David Carter, M.D.
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313 East Anderson Lane #200
Austin, TX 78752

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.: 5
RANDOMIZATION NUMBER: R5001
PATIENT INITIALS: (b) (6)
VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:40 DATE: 15-Apr-2007
DATE RECEIVED IN LABORATORY: 17-Apr-2007
DATE REPORTED BY LABORATORY: 26-Apr-2007
SEX: M BIRTHDATE: (b) (6) AGE: 36
SCREENING NUMBER: S5011

Is this Clinically
Significant/ Adverse
Event?

Yes No

URINE CREATININE, 24 HR

U24h Creat	1764	800-1800 mg/24hr
UAlq24Crea	72.0	mg/dL No Ref Rng

ELAPSED DATE AND TIME, 24HR


Elpsd D&T	1440	min
-----------	------	-----

24 HR COLLECTION INFORMATION

Start Date	15-Apr-2007
Start Time	15:40
Stop Date	16-Apr-2007
Stop Time	15:40

TOTAL 24HR URINE VOLUME

Total Vol.	2450	mL
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Investigator Signature:

28 Apr 07
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

B17181

(INV)