

# CRF Report for Study E6270229

Patient: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Header\_Page

Blank? N

CRF Page #: 1

Visit: SCREENING

Visit Date: 03-04-2007

Document #: R157748613

Entered By: Laura Vol

Entry Time: 20-09-2007 12:05:10

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 20-09-2007 12:07:07

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Header\_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 03-04-2007

Entered By: Laura Vol

Entry Time: 20-09-2007 12:05:10

Last Modification Time: 20-09-2007 12:07:07

Page number: 1

RDC CASE REPORT FORM

SMOKER

Sponsor Name

Investigator

Site

RJ REYNOLDS TOBACCO COMPANY

DAVID CARTER, M.D.

AUSTIN

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

age ID: D11870313

/ Covance No. 6270-229

Data Clarification Form

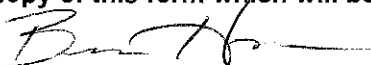
o:Covance CRU Austin  
Investigator:David Carter  
ate:03-APR-2008

Patient#:5012  
Patient Initials:  
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
aboratory Evaluation AB_UNSCHE Disc ID: 1374695113 Type: MANUAL	29 27APR07 Closed: N	Disc ID 1297769613 added lab req #O958598 to the unsched lab assessment page. This lab req is the scheduled W2 Carboxyhemoglobin result for which the req # is not to be recorded in the crf.	<input checked="" type="checkbox"/> Delete req #O958598 from unsched assessment <input type="checkbox"/> Other:_____

19m2  
040908

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

  
Authorized Personnel Signature

04 APR 2008  
Date

age ID: D11767213

/ Covance No. 6270-229

Data Clarification Form

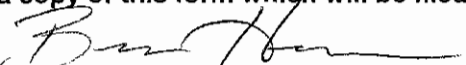
o: Covance CRU Austin  
Investigator: David Carter  
ate: 19-MAR-2008

Patient#: 5012  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Proventil Administration WEEK 24 (EOS) Disc ID: 1347149313 Type: MANUAL	24 31JUL07 Closed: N	Please provide updates to the Proventil Administration and Postbronchodilator Spirometry as these assessments were ND.	<input checked="" type="checkbox"/> Data fields=ND <input type="checkbox"/> Data modules=BLANK? Y <input type="checkbox"/> Other: _____

JP  
25-MAR-08

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

  
Authorized Personnel Signature

21 MAR 2008  
Date

age ID: D11307613

/ Covance No. 6270-229

Data Clarification Form

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

Patient#:5012  
Patient Initials:  
Reviewer:Dawn Taylor

orm Name / Visit Name	Page # Date	Questions/Comments	Resolution
Used Study Tobacco-Heating Cigarette Collection VEEK 24 (EOS) Disc ID: 1295163413 Type: MANUAL HEADER	24 31JUL07 Closed: N	As this subject was randomized to SNUS, please confirm that the W24 'Usual Study Tobacco-Heating Cigarette Collection' module is to be marked as 'Blank'.	<input checked="" type="checkbox"/> Update module Blank?=Y [ ] Other:_____
Usual Brand Cigarette Butt Collection VEEK 0 (BASELINE) Disc ID: 1296737013 Type: MANUAL	5.1 27APR07 Closed: N	Response to the W0 'Usual Brand Cigarette Butt Collection' Any Product Deviation? Question is 'No', however response is provided for 'If yes, number of butts other than usual brand' is provided.	<input checked="" type="checkbox"/> Delete 'N/A' [ ] Other:_____

Pma  
021807

Pma  
021807

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received a copy of this form which will be filed with my copy of the appropriate Case Report Form.

Amanda Lynn  
Authorized Personnel Signature

30-Jan-2008  
Date

age ID: D11306813

/ Covance No. 6270-229

Data Clarification Form

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

Patient#: 5012  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
4-Hour Urine Collection WEEK 0 (BASELINE) Disc ID: 1295113113 Type: MANUAL	5 26APR07 Closed: N	W0 Spot Urine Collection notes a start time of 15:20 while the 0-24H Urine Collection notes a start time of 15:30. Please verify the collection times. <i>also the stop time urine collection needs to be changed to 15:23 please update.</i>	Spot Urine Start Time <input checked="" type="checkbox"/> 15:20 <input type="checkbox"/> 15:30  0-24 Hour Start Time <input checked="" type="checkbox"/> 15:20 <input type="checkbox"/> 15:30
Alcohol Screen WEEK 24 (EOS) Disc ID: 1295119613 Type: MANUAL	23 31JUL07 Closed: N	The date currently provided for the W24 Alcohol Screen is 09-08-2007. Please verify this date.	<input checked="" type="checkbox"/> 31-07-2007 <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.

*Amelia Lynn*  
Authorized Personnel Signature

30-Jan-2008  
Date

age ID: D11306913

/ Covance No. 6270-229

Data Clarification Form

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

Patient#: 5012  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Laboratory Evaluation WEEK 0 (BASELINE) Disc ID: 1295143113 Type: MANUAL	5 26APR07 Closed: N	1) Lab paperwork for W0 Lab evaluations was not received. Please provide.  2) Requisition Number 1 and 2 are the same (#0578086). Please confirm second Requisition Number or removal of the duplicate entry.	1) <input checked="" type="checkbox"/> W0 lab documents are attached to this DCF  [ ] Other: _____  2) <input checked="" type="checkbox"/> Requisition Number 2: <u>0746675</u>  [ ] Remove entry from Requisition Number 2 field.
Laboratory Evaluation SCREENING Disc ID: 1295150313 Type: MANUAL HEADER	2 03APR07 Closed: N	On the Screening lab requisition (#0482306) the Date of Birth is recorded as (b) (6). CRF lists DOB as (b) (6). Please reconcile.	<input checked="" type="checkbox"/> DOB is (b) (6). Lab paperwork updated. Req attached.  [ ] Other: _____

*Originality for window stop crf = 1520, lab = 1523 DMD 021908*

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*Amanda Lign*  
Authorized Personnel Signature

30-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. 0578086

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: 24 HR UR

## SPONSOR REPORT TO:

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

24 Hr Urine Collection

COLLECTION TIME: 15:20 DATE: 26-Apr-2007

DATE RECEIVED IN LABORATORY: 28-Apr-2007

DATE REPORTED BY LABORATORY: 30-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## URINE CREATININE, 24 HR

U24h Creat 615 L 800-1800 mg/24hr  
UAlc24Crea 77.0 mg/dL No Ref Rng

[ ]

[✓]

## ELAPSED DATE AND TIME, 24HR

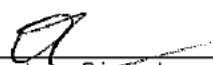
Elpsd D&amp;T 1443 min

## 24 HR COLLECTION INFORMATION

Start Date 26-Apr-2007  
Start Time 15:20  
Stop Date 27-Apr-2007  
Stop Time 15:23

## TOTAL 24HR URINE VOLUME

Total Vol. 800 mL

  
Investigator Signature:

03 May 07  
Date:

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

(INV)

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

ACCESSION NO. 0746625

Page 1 of 1

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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: 07:23 DATE: 27-Apr-2007  
DATE RECEIVED IN LABORATORY: 27-Apr-2007  
DATE REPORTED BY LABORATORY: 03-May-2007  
SEX: M BIRTHDATE: (b) (6) AGE: 34  
SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

  
Investigator Signature:

04 May 07  
Date:

B17181

(INV)



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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

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3402 Kinsman Boulevard  
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SEX: M BIRTHDATE: (b) (6) AGE: 34  
SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

**HEMOGLOBIN A1C**

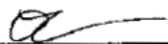
Hgb A1c 5.3

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

  
Investigator Signature:

04 May 07  
Date:

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B17181

(INV)

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**LABORATORY REPORT**

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INVESTIGATOR NO.: 5

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VISIT: 2

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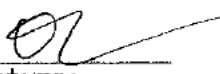
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**LIPID PANEL**

Triglycer	106	50-321 mg/dL
Cholest	182	150-264 mg/dL
HDL Dex-S	45	29-62 mg/dL
LDL Chol	116	78-185 mg/dL

  
Investigator Signature:

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Madison, WI United States 53704

PROTOCOL 6270-229

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VISIT: 2

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042


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Significant/ Adverse  
Event?

Yes

No

OXIDIZED LDL

Oxidize LDL To follow

  
Investigator Signature:

04 May 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)

**Covance CLS**

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**LABORATORY REPORT**

ACCESSION NO. 0746625

Page 1 of 3

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PROTOCOL 6270-229

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Madison, WI United States 53704

Week 0

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SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	70		31-129 U/L
ALT (SGPT)	14		6-43 U/L
AST (SGOT)	20		11-36 U/L
GGT	28		10-61 U/L
LDH	161		53-234 U/L
Urea Nitr	7		4-24 mg/dL
Creatinine	1.3	H	0.5-1.2 mg/dL
Glucose	83		70-115 mg/dL
Uric Acid	5.1		2.1-8.2 mg/dL
Calcium	10.0		8.3-10.6 mg/dL
Phosphorus	3.3		2.2-5.1 mg/dL
Total Prot	7.6		6.1-8.4 g/dL
Albumin	4.5		3.3-4.9 g/dL
Sodium	143		132-147 mEq/L
Potassium	4.5		3.4-5.4 mEq/L
Chloride	105		94-112 mEq/L

[ ]

[x]

Investigator Signature:

04 May 07  
Date:

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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 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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Is this Clinically  
 Significant/ Adverse  
 Event?

Yes

No

**HEMATOLOGY& DIFFERENTIAL PANEL**

HGB	15.6		12.7-18.1 g/dL
HCT	45		39-54 %
RBC	5.0		4.5-6.4x10 <sup>6</sup> /uL
MCV	91		79-96 fL
MCH	32		26-34 pg
MCHC	35		31-38 g/dL
RDW	13.8		12.0-15.0 %
RBC Morph	Normocytic		
WBC	7.03		3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	2.66		1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	3.81		0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.42		0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.09		0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.05		0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	37.8	L	40.5-75.0 %
Lymphocyte	54.2	H	15.4-48.5 %
Monocytes	6.0		2.6-10.1 %
Eosinophil	1.3		0.0-6.8 %
Basophils	0.7		0.0-2.0 %
Platelets	289		140-400 x10 <sup>3</sup> /uL

[ ]

[✓]

[ ]

[✓]

Investigator Signature:

Date:

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Covance-Austin  
313 East Anderson Lane #200  
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PROTOCOL 6270-229

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SPONSOR REPORT TO:

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Medical Director  
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Madison, WI United States 53704

Week 0

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Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**URINE MACRO & MICRO PANEL**

Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.006	1.003-1.035
pH	5.0	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Trace H	Ref Rng: Negative
Microscop	Positive WBCs	

[ ]

[X]

**CELLULAR ELEMENTS**

WBC	1	0-5 /HPF
-----	---	----------

*OC*  
Investigator Signature:

*04 May 07*  
Date:

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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

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL IRON

Total Iron 106 45-160 ug/dL

## C-REACTIVE PROTEIN

CRP-HS 0.046 <=0.287 mg/dL

## CARBOXYHEMOGLOBIN

Carboxyhem 3.6 % saturation  
No Ref Rng

*a*  
Investigator Signature:

04 May 07  
Date:

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SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HOMOCYSTEINE**


\*1 HCY

41.08 H 5.90-16.00 umol/L

[ ]

[x]

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

  
Investigator Signature:

04 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**

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

ACCESSION NO. 0746625

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 CRJ, 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: 07:23 DATE: 27-Apr-2007

DATE RECEIVED IN LABORATORY: 27-Apr-2007

DATE REPORTED BY LABORATORY: 03-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

**FIBRINOGEN**

Fibrinogen

272

200-400 mg/dL

  
Investigator Signature:

04 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)

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**LABORATORY REPORT**

ACCESSION NO. 0746625

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: 07:23 DATE: 27-Apr-2007

DATE RECEIVED IN LABORATORY: 27-Apr-2007

DATE REPORTED BY LABORATORY: 03-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

## URINE CREATININE, SPOT

Rnd Ur Crt 47

mg/dL No Ref Rng

  
Investigator Signature:

04 May 07  
Date:

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

B17181

(INV)

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**LABORATORY REPORT**

ACCESSION NO. 0746625

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: 07:23 DATE: 27-Apr-2007

DATE RECEIVED IN LABORATORY: 27-Apr-2007

DATE REPORTED BY LABORATORY: 03-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

sICAM-1

sICAM-1

254

115-306 ng/mL

  
Investigator Signature:

04 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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Tel. +1 (800) 327 7270  
**LABORATORY REPORT**

ACCESSION NO. 0746625  
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: 07:23 DATE: 27-Apr-2007

DATE RECEIVED IN LABORATORY: 27-Apr-2007

DATE REPORTED BY LABORATORY: 03-May-2007

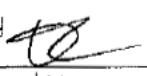
SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?  
Yes No

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

Note #1 - Specimen received beyond stability

  
Investigator Signature:

04 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)

LOCATION: Covance CLS

Covance CLS  
RX TIME 05/04 '07 03:48

age ID: D11307013

/ Covance No. 6270-229

Data Clarification Form

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

Patient#:5012  
Patient Initials:  
Reviewer:Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
laboratory Evaluation AB_UNSCHE Disc ID: 1297769613 Type: MANUAL HEADER	29 27APR07 Closed: N	Please address the following regarding the Unscheduled Lab Eval module:  1-Req #O958598 is not recorded. Please confirm addition of this req.  2-Lab evaluations for Req #O062495 were not clinically significant, however Test Name and Lab Name fields are entered. Please reconcile.	1- <input checked="" type="checkbox"/> Add to Unscheduled Lab Eval Module: Date: 11-05-2007 Requisition Number: O958598 Clinically Significant?: No [ ] Other: _____  2- <input checked="" type="checkbox"/> Remove from Req # O062495 data line: Test name: Urine Macro and Micro Panel Lab name: Covance CLS [ ] Other: _____
laboratory Evaluation AB_UNSCHE Disc ID: 1295143513 Type: MANUAL HEADER	29 27APR07 Closed: N	Lab paperwork for the 27-04-2007 Unscheduled Lab Evaluation (#O062495) was not received. Please provide.	<input checked="" type="checkbox"/> Requisition #O062495 lab paperwork is attached to this DCF  [ ] 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

30-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. 0062495

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

Retest

COLLECTION TIME: 15:23 DATE: 27-Apr-2007

DATE RECEIVED IN LABORATORY: 28-Apr-2007

DATE REPORTED BY LABORATORY: 28-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**URINE MACRO & MICRO PANEL**

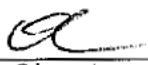
Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.018	1.003-1.035
pH	7.0	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive <i>NCS</i>	

**CELLULAR ELEMENTS**

RBC	1 <i>NCS</i>	0-3 /HPF
WBC	2 <i>NCS</i>	0-5 /HPF

**MISCELLANEOUS ELEMENTS**

Mucous	Present <i>NCS</i>	Ref Rng: Not present
--------	--------------------	----------------------

  
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)

age ID: D11307113

/ Covance No. 6270-229

Data Clarification Form

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

Patient#: 5012  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Oral Health Examination WEEK 0 (BASELINE) Disc ID: 1295118613 Type: MANUAL	5 26APR07 Closed: N	Date of W0 Oral Health Examination is recorded twice. Please confirm removal of the duplicate entry.	<input checked="" type="checkbox"/> Confirmed, remove duplicate date entry. <input type="checkbox"/> Other: _____
Oral Health Examination WEEK 24 (EOS) Disc ID: 1295119013 Type: MANUAL	23 31JUL07 Closed: N	Date of W24 Oral Health Examination is recorded twice. Please confirm removal of the duplicate entry.	<input checked="" type="checkbox"/> Confirmed, remove duplicate date entry. <input type="checkbox"/> Other: _____

JAC  
15APR08

JAC  
15JUL08

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

30-Jan-2008  
Date

age ID: D11307213

/ Covance No. 6270-229

Data Clarification Form

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

Patient#:5012  
Patient Initials:  
Reviewer:Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Post-Bronchodilator Best Spirometry Test Result WEEK 24 (EOS) Disc ID: 1295141613 Type: MANUAL	24 31JUL07 Closed: N	1) The date currently provided for the W24 Post- Bronchodilator Spirometry Test is 09-08-2007. Please verify this date.  2) Please verify Study Completion date.	1) [ ] 31-07-2007 [X] Other: <u>09-08-2007</u> subject came late to finish ET visit.  2) [ ] 31-07-2007 [X] 09-08-2007 [ ] Other: _____

DAE  
15Feb08  
  
DAE  
15Feb08

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.

Dawn Taylor  
Authorized Personnel Signature

30-Jan-2008  
Date



age ID: D11307313

/ Covance No. 6270-229

Data Clarification Form

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

Patient#: 5012  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Pre-Bronchodilator Best Baseline Spirometry Test Result WEEK 24 (EOS) Disc ID: 1295120713 Type: MANUAL	24 31JUL07 Closed: N	1) The date currently provided for the W24 Pre-Bronchodilator Spirometry Test is 09-08-2007. Please verify this date.  2) Please verify Study Completion date.	1) [ ] 31-07-2007 [x] Other: <u>09-08-2007</u>  2) [ ] 31-07-2007 [x] 09-08-2007 [ ] Other: _____

Alma  
02/08/08

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

Chavanda Lynn  
Authorized Personnel Signature

30-Jan-2008  
Date

age ID: D11307413

/ Covance No. 6270-229

Data Clarification Form

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

Patient#: 5012  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Pregnancy Test WEEK 24 (EOS) Disc ID: 1295121113 Type: MANUAL	23 31JUL07 Closed: N	For consistency across subjects and sites, please confirm that, although this is a Male subject, 'Pregnancy Test Date' should be populated with the visit date.	<input checked="" type="checkbox"/> 31-07-2007 <input type="checkbox"/> Other: _____
Pro Questionnaires WEEK 0 (BASELINE) Disc ID: 1295108913 Type: MANUAL	5 26APR07 Closed: N	The date currently provided for the W0 Pro Questionnaires DCM is 26-07-2007. Please verify this date.	<input checked="" type="checkbox"/> 26-04-2007 <input type="checkbox"/> Other: _____

042  
15 Feb 08  
042  
15 Feb 08

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

Amanda Lynn  
Authorized Personnel Signature

30-Jan-2008  
Date

age ID: D11307513

/ Covance No. 6270-229

Data Clarification Form

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

Patient#: 5012  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Urine Drug Screen WEEK 24 (EOS) Disc ID: 1297797613 Type: MANUAL	23 31JUL07 Closed: N	The date currently provided for the W24 Drug Screen is 'ND'. Please provide actual date.	<input checked="" type="checkbox"/> 31-07-2007 [ ] Other: _____
Used Study Snus Collection WEEK 24 (EOS) Disc ID: 1297818413 Type: MANUAL	24 31JUL07 Closed: N	Response to the W24 24H Prior to Check-In and 24H In-House 'Used Study Snus Collection' Any Product Deviation? Question is 'NA', however response is provided for 'If yes, number of butts other than usual brand.' Please reconcile.	<input checked="" type="checkbox"/> Delete 'N/A' [ ] Other: _____

On  
15 Jan 08  
Dmd  
021801

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

30-Jan-2008  
Date

# CRF Report for Study E6270229

Patient: 5012  
 CRF: Screening  
 Visit: SCREENING  
 Entered By: Ben Heyen  
 Discrepancies: Closed  
 Approval Status: Not Approved  
 Verification: Not Verified  
 Comment:

Site: CA\_001  
 Blank? N  
 Visit Date: 03-04-2007  
 Entry Time: 23-09-2007 11:42:10  
 Modification Time: 20-12-2007 22:34:33  
 Approval Time:  
 Verification Time:

Investigator: C2785\_03  
 CRF Page #: 2  
 Document #: R158080513  
 CRF Status: Entry Complete  
 Approver:  
 Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 03-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 11:42:10	
		Last Modification Time: 16-11-2007 14:19:54	
		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: 03-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 11:42:10	
		Last Modification Time: 23-09-2007 12:05:00	
		Page number: 20	

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

# CRF Report for Study E6270229

Patient: 5012

CRF: Screening

Visit: SCREENING

Site: CA\_001

Blank? N

Visit Date: 03-04-2007

Investigator: C2785\_03

CRF Page #: 2

Document #: R158080513

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

Section: Exc_Criteria	3 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 03-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 11:42:10	
		Last Modification Time: 23-09-2007 12:05:00	
		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 Investsigator(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: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 03-04-2007

Document #: R158080513

Section: Informed_Consent	4 of 10	Blank? N	Section Date: 03-04-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 23-09-2007 11:42:10	
Entered By: Ben Heven			Last Modification Time: 23-09-2007 12:05:00	
			Page number: 4	
Informed Consent				
Date the Subject Signed the Smoker Informed Consent Form 03-04-2007				

Section: Elig	5 of 10	Blank? N	Section Date: 03-04-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 23-09-2007 11:42:10	
Entered By: Ben Heven			Last Modification Time: 23-09-2007 12:05:00	
			Page number: 4	
Subject Eligibility				
Did the subject meet all of the inclusion criteria?		YES		
Did the subject have any of the exclusion criteria?		NO		
Criteria Type	Criteria Number	Deviation	Date Exemption	Granted

Section: Patient_Rep_Outc	6 of 10	Blank? N	Section Date: 03-04-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 23-09-2007 11:42:10	
Entered By: Ben Heven			Last Modification Time: 17-12-2007 22:36:24	
			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 Date: 03-04-2007	Section Status: Entry Complete
Visit: SCREENING			Entry Time: 23-09-2007 11:42:10	
Entered By: Ben Heven			Last Modification Time: 23-09-2007 12:05:00	
			Page number: 5	
Demographics		Subject Initials		
Date of Birth	Gender	Height	Height Unit	Weight
(b) (6)	M	174.3	CM	072.7
		xxx.x		xxx.x
Ethnicity				

# CRF Report for Study E6270229

Patient: 5012

CRF: Screening

Visit: SCREENING

Site: CA\_001

Blank? N

Visit Date: 03-04-2007

Investigator: C2785\_03

CRF Page #: 2

Document #: R158080513

Section: Demog 7 of 10

Hispanic or Latino?  
NO

Race  
BLACK

Race other

Section: Vital 8 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 03-04-2007

Entered By: Ben Heyen

Entry Time: 23-09-2007 11:42:10

Last Modification Time: 23-09-2007 12:05:00

Page number: 5

## VITAL SIGNS

Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit
0738	Systolic 129	Diastolic 80	61	16	35.9	C
					xxx.x	

Comments

Section: Hdvt\_Oral\_Health 9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 03-04-2007

Entered By: Ben Heyen

Entry Time: 23-09-2007 11:42:10

Last Modification Time: 20-12-2007 22:34:33

Page number: 5

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

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

Section: Lab\_Eval 10 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 03-04-2007

Entered By: Ben Heyen

Entry Time: 23-09-2007 11:42:10

Last Modification Time: 20-11-2007 14:04:23

Page number: 6

## Laboratory Evaluations

Were the scheduled laboratory samples obtained?	YES	No, specify
Requisition Number 1	O482306	
Requisition Number 2 (if applicable)	O478659	
Were there any clinically significant labs?	NO	(Yes, specify below)
Requisition Number	Test Name	H/L Lab ID Lab Name

# CRF Report for Study E6270229



Patient: 5012  
CRF: Screening2  
Visit: SCREENING  
Entered By: Ben Heven  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified

Site: CA\_001  
Blank? N  
Visit Date: 03-04-2007  
Entry Time: 23-09-2007 12:06:49  
Modification Time: 17-12-2007 22:39:16  
Approval Time:  
Verification Time:

Investigator: C2785\_03  
CRF Page #: 3  
Document #: R158080713  
CRF Status: Entry Complete

Approver:  
Verifier:

## Comment:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 03-04-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 12:06:49	
		Last Modification Time: 23-09-2007 12:18:45	
		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: 03-04-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 12:06:49	
		Last Modification Time: 23-09-2007 12:43:54	
		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: 03-04-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 12:06:49	
		Last Modification Time: 23-09-2007 12:44:23	
		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: 03-04-2007	



# CRF Report for Study E6270229

Patient: 5012

CRF: Screening2

Visit: SCREENING

Site: CA\_001

Blank? N

Visit Date: 03-04-2007

Investigator: C2785\_03

CRF Page #: 3

Document #: R158080713

Section: Med\_Hx 4 of 10

Entered By: Ben Heyen

Entry Time: 23-09-2007 12:06:49

Last Modification Time: 23-09-2007 12:31:48

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: 03-04-2007

Entered By: Ben Heyen

Entry Time: 23-09-2007 12:06:49

Last Modification Time: 20-11-2007 14:05:54

Page number: 8

## 12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

0744

58

### Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

212

88

396

393

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: 03-04-2007

Entered By: Ben Heyen

Entry Time: 23-09-2007 12:06:49

Last Modification Time: 17-12-2007 22:39:16

Page number: 9

## USUAL BRAND CIGARETTE PACK

## DATA

Usual Brand  
NEWPORT

Type  
MENTHOL

Length  
KING SIZE 83-85MM

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

Style  
REGULAR

Pack  
HARD

4 months

15 years

Section: Ftc\_Tar\_Level 7 of 10

Blank? N

Section Status: Entry Complete

# CRF Report for Study E6270229

Patient: 5012

CRF: Screening2

Visit: SCREENING

Site: CA\_001

Blank? N

Visit Date: 03-04-2007

Investigator: C2785\_03

CRF Page #: 3

Document #: R158080713

Section: Ftc_Tar_Level	7 of 10	Section Date: 03-04-2007
Visit: SCREENING		Entry Time: 23-09-2007 12:06:49
Entered By: Ben Heyen		Last Modification Time: 23-09-2007 12:40:12
Page number: 9		
FTC TAR LEVEL OF USUAL BRAND		
FTC Tar Level (mg)		
10.3		

Section: Expired_Carbon_M	8 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 03-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 12:06:49	
		Last Modification Time: 23-09-2007 12:40:12	
Page number: 10			
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
0733	14	02.8	

Section: Best_Baseline_Sp	9 of 10	Blank? N	Section Status: Entry Complete		
Visit: SCREENING		Section Date: 03-04-2007			
Entered By: Ben Heyen		Entry Time: 23-09-2007 12:06:49			
		Last Modification Time: 23-09-2007 12:40:12			
Page number: 10					
BEST BASELINE SPIROMETRY TEST RESULT					
Actual Time	Testing Position	FEV1 L	FEV 1 Predicted (%)	FVC Predicted (%)	Comments
of FEV1/FVC Test					
1028	STANDING	3.59	94	5.29	114

Section: Irvs_Training	10 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 03-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 12:06:49	
		Last Modification Time: 23-09-2007 12:40:12	
Page number: 10			
IVRS TRAINING			
Did Subject receive training on the Daily Call-In Diary (IVRS)?			
YES			

# CRF Report for Study E6270229

Patient: 5012

CRF: Week-2

Visit: WEEK -2

Entered By: Ben Heyen

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 27-04-2007

Entry Time: 23-09-2007 12:44:31

Modification Time: 23-09-2007 12:46:06

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 4

Document #: R158081113

CRF Status: Entry Complete

Approver:

Verifier:

Section: Usual\_Brand\_Coll

Blank? N

Section Status: Entry Complete

Visit: WEEK -2

Section Date: 27-04-2007

Entered By: Ben Heyen

Entry Time: 23-09-2007 12:44:31

Last Modification Time: 23-09-2007 12:46:06

Page number: 11

## USUAL BRAND

## CIGARETTE COLLECTION TRAINING

1. Did subject receive foam block?

YES

2. Did subject receive training on usual brand collection?

YES

3. Was subject provided usual brand cigarettes for Week 0  
cigarette butt collection?

YES

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Entered By: Ben Heven

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 26-04-2007

Entry Time: 23-09-2007 13:22:45

Modification Time: 21-11-2007 12:19:38

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 5

Document #: R158084813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 13:22:45	
		Last Modification Time: 23-09-2007 13:30:01	
		Page number: 12A	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject	YES / NO	
26-07-2007	complete Smoker Routine Questionnaire PRIOR to any		
	study procedures being performed?	YES	

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 13:22:45	
		Last Modification Time: 23-09-2007 13:49:24	
		Page number: 12A	
Drug Screen			
Date	Drug Screen Result		
26-04-2007	NEG		

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 13:22:45	
		Last Modification Time: 23-09-2007 13:50:45	
		Page number: 12A	
Alcohol Screen			
Date	Breathalyzer Result		
26-04-2007	NEG		

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 13:22:45	
		Last Modification Time: 20-11-2007 15:59:19	
		Page number: 12A	

# CRF Report for Study E6270229

Patient: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 26-04-2007

Document #: R158084813

Section: Preg_Test		4 of 11	
Pregnancy Test			
Date	Result		
26-04-2007	N/A, MALE OR FEMA LE		

Section: Urine_Coll		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007					
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:22:45					
		Last Modification Time: 20-11-2007 14:09:31					
		Page number: 12A					
24-Hour Urine Collection							
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments	
SPOT URINE VOID	26-04-2007	1520	NA	NA	NA		
0 HOUR TO 24 HOURS	26-04-2007	1530	27-04-2007	1520	800		

Section: Hdyf_Oral_Health		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007					
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:22:45					
		Last Modification Time: 20-11-2007 14:24:10					
		Page number: 13.1					
HDYF? INQUIRY							
Date	Actual Time	HDYF Performed?		Comments			
27-04-2007	0623	YES					

Section: Vital		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007					
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:22:45					
		Last Modification Time: 23-09-2007 13:48:06					
		Page number: 13.1					
VITAL SIGNS							
Blood Pressure							
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
26-04-2007	1531	123	78	68	10	ND	NA

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CA\_001

Blank? N

Visit Date: 26-04-2007

Investigator: C2785\_03

CRF Page #: 5

Document #: R158084813

Section: Vital	7 of 11
Comments	xxx.x

Section: Oral_Health_Exam	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:22:45	
		Last Modification Time: 20-11-2007 14:28:42	
		Page number: 13.1	
ORAL HEALTH EXAMINATION			
Date			
27-04-2007			
27-04-2007			
	Procedure	Relevant Findings?*	Findings
	ORAL HEALTH QUESTIONS PERFORMED	NO	
	EVIDENCE OF LEUKOPLAKIA	NO	
	OTHER ORAL KERATOSIS	NO	

Section: Phys_Exam	9 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 26-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:22:45	
		Last Modification Time: 23-09-2007 13:43:37	
		Page number: 14.1	
PHYSICAL EXAMINATION			
Date			
27-04-2007			
	Code Number	Code	Relevant Findings? Findings
	01	GENERAL	NO
	02	SKIN	NO
	03	HEENT	NO
	04	MOUTH	NO
	05	NECK	NO
	06	THORAX/LUNG	NO
	07	CARDIO	NO
	08	ABDOMEN	NO
	09	MUSCULO	NO
	10	NEURO	NO
	11	LYMPH	NO
	12	OTHER	NA

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CA\_001

Blank? N

Visit Date: 26-04-2007

Investigator: C2785\_03

CRF Page #: 5

Document #: R158084813

Section: Weight_Height	10 of 11	Blank? N	Section Date: 26-04-2007	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Entry Time: 23-09-2007 13:22:45		
Entered By: Ben Heyen		Last Modification Time: 23-09-2007 13:43:37		
		Page number: 14.1		

WEIGHT & HEIGHT				
Date	Weight	Unit	Height	Unit
26-04-2007	073.6	KG	NA	
	xxx.x		xxx.x	

Section: Lab_Eyal	11 of 11	Blank? N	Section Date: 26-04-2007	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Entry Time: 23-09-2007 13:22:45		
Entered By: Ben Heyen		Last Modification Time: 20-11-2007 14:30:46		
		Page number: 15.1		

Laboratory Evaluations				
Date				
26-04-2007				
Were the scheduled laboratory samples obtained?	YES	No, specify		
Requisition Number 1	O578086			
Requisition Number 2 (if applicable)	O578086			
Were there any clinically significant labs?	NO	(Yes, specify below)		
Requisition Number	Test Name	H/L	Lab ID	Lab Name

# CRF Report for Study E6270229



Patient: 5012

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Entered By: Ben Heyen

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 27-04-2007

Entry Time: 23-09-2007 13:50:50

Modification Time: 20-12-2007 22:35:28

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 5.1

Document #: R158087413

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:50:50	
		Last Modification Time: 23-09-2007 13:56:27	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
27-04-2007	0720		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:50:50	
		Last Modification Time: 23-09-2007 13:56:27	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
27-04-2007	1446	10	03.1

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:50:50	
		Last Modification Time: 23-09-2007 13:56:27	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
27-04-2007	1516		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:50:50	
		Last Modification Time: 17-12-2007 23:44:34	
		Page number: 16.1	



# CRF Report for Study E6270229

Patient: 5012

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CA\_001

Blank? N

Visit Date: 27-04-2007

Investigator: C2785\_03

CRF Page #: 5.1

Document #: R158087413

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time		Testing		FVC			
of FEV1/FVC							
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
27-04-2007	1535	STANDI	3.51	91	5.01	108	
		NG					

Section: Proventil_Admin	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:50:50	
		Last Modification Time: 23-09-2007 13:56:27	
		Page number: 16.1	
PROVENTIL ADMINISTRATION			
	Actual Time of Proventil Administration	Amount Administered	Comments
Date			
27-04-2007	1545	2 METERED PUFFS	

Section: Post_Bronch_Spir	6 of 11	Blank? N	Section Status: Entry Complete				
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007					
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:50:50					
		Last Modification Time: 23-09-2007 13:56:27					
		Page number: 16.1					
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
	Actual Time of FEV1/FVC	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						
27-04-2007	1600	STANDING	3.74	97	4.87	105	

Section: Unused_Usual_Bra	7 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:50:50	
		Last Modification Time: 23-09-2007 13:56:27	
		Page number: 17.1	
Unused Usual Brand Cigarette Pack Collection			
			Yes / No
Date	Does Site have 5 unopened packs of subject's usual		
27-04-2007	brand cigarette to ship to CCLS?		YES

# CRF Report for Study E6270229

Patient: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 27-04-2007

Document #: R158087413

Section: Usual Brand Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007		Entry Time: 23-09-2007 13:50:50			
Entered By: Ben Heyen		Last Modification Time: 20-12-2007 22:35:28		Page number: 17.1			

Usual Brand Cigarette Butt Collection					Number of Usual Brand Cigarette Butts Collected	Any Product Deviation?	If yes, number of butts other than usual brand:	Comments
Scheduled Collection Period	Start Date	Start Time	Stop Date	Stop Time				
24 HOURS PRIOR TO CHECK-IN	25-04- 2007	1430	26-04-2007	1459	13	NO	NA	
24 HOURS IN-HOUSE	26-04- 2007	1459	27-04-2007	1500	10	NO	NA	

Section: Used Butt Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007		Entry Time: 23-09-2007 13:50:50			
Entered By: Ben Heyen		Last Modification Time: 23-09-2007 17:05:23		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT		
Date	Scheduled Collection Period	
25-04-2007	24 HOURS PRIOR TO CHECK-IN	

Cigarette Butt Number	Cigarette Butt Measurement (mm)
1	40
2	40
3	32
4	30
5	39
6	40
7	27
8	31
9	25
10	43
11	39
12	36
13	40

Section: Used Butt Measur		10 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 27-04-2007		Entry Time: 23-09-2007 13:50:50			
Entered By: Ben Heyen							

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CA\_001

Blank? N

Visit Date: 27-04-2007

Investigator: C2785\_03

CRF Page #: 5.1

Document #: R158087413

Section: Used\_Butt\_Measur 10 of 11

Last Modification Time: 23-09-2007 17:05:23

Page number: 19.1

## USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date  
26-04-2007

Period  
24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1  
2  
3  
4  
5  
6  
7  
8  
9  
10

34  
32  
27  
30  
28  
30  
35  
25  
30  
24

Section: Randomization 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 27-04-2007

Entered By: Ben Heven

Entry Time: 23-09-2007 13:50:50

Last Modification Time: 23-09-2007 17:05:23

Page number: 20.1

## RANDOMIZATION

Date  
27-04-2007

Actual Time  
1604

Randomization Sequence  
GROUP B

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 0 3baseline

Visit: WEEK 0 (BASELINE)

Entered By: Ben Heyen

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 27-04-2007

Entry Time: 23-09-2007 13:56:28

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

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 5.2

Document #: R158087613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study\_Prod\_Dispe

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 27-04-2007

Entered By: Ben Heyen

Entry Time: 23-09-2007 13:56:28

Last Modification Time: 20-11-2007 15:51:37

Page number: 23.1

## STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
27-04-2007	1615	SNUS	ORIGINAL	3
27-04-2007	1615	SNUS	FROST	1
27-04-2007	1615	SNUS	SPICE	1

# CRF Report for Study E6270229

Patient: 5012

CRF: Intercurrent\_III

Visit: INTERCURRENT ILL

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 27-04-2007

Entry Time: 23-09-2007 13:58:10

Modification Time: 23-09-2007 13:58:30

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 7

Document #: R158087713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip\_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 27-04-2007

Entered By: Ben Heven

Entry Time: 23-09-2007 13:58:10

Last Modification Time: 23-09-2007 13:58:30

Page number: 21

## Intercurrent Illness/Physical Findings

Did the subject experience any intercurrent illness/findings from Screening to the first use of study product?

NO

Event No	Illness/Finding	Date	Onset Time	Resolved / Changed Date	Time	Severity	Relationship to Procedure	Action Taken
----------	-----------------	------	---------------	----------------------------	------	----------	------------------------------	--------------

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 1

Visit: WEEK 1

Entered By: Ben Heven

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 04-05-2007

Entry Time: 23-09-2007 13:58:46

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

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 8

Document #: R158087913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 04-05-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 13:58:46	
		Last Modification Time: 27-11-2007 23:38:14	
		Page number: 22	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions Performed?	Comments
Actual Time	HDYF Performed?		
1213	YES	ND	

Section: Vital	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 04-05-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 13:58:46	
		Last Modification Time: 23-09-2007 14:02:49	
		Page number: 22	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
1219	126	84	61
			Respiratory Rate
			12
			Temperature
			36.4
			xxx.x
			Unit
			C
Comments			

Section: Expired_Carbon_M	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 04-05-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 13:58:46	
		Last Modification Time: 23-09-2007 14:02:49	
		Page number: 22	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1217	21	03.9	

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

Patient: 5012  
CRF: Week 1  
Visit: WEEK 1

Site: CA\_001  
Blank? N  
Visit Date: 04-05-2007

Investigator: C2785\_03  
CRF Page #: 8  
Document #: R158087913

Section: Unused_Study_Pro	4 of 5	Section Date: 04-05-2007
Visit: WEEK 1		Entry Time: 23-09-2007 13:58:46
Entered By: Ben Heyen		Last Modification Time: 27-11-2007 23:38:38
Page number: 23		
Unused Study Product Returned		
Product Returned	Flavor	Amount Returned
Packs	Individual Cigarettes / pouches	
ND	ND	ND

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 04-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 13:58:46	
		Last Modification Time: 25-09-2007 22:45:00	
Page number: 23			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1229	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 2

Visit: WEEK 2

Entered By: Ben Heyen

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Site: CA\_001

Blank? N

Visit Date: 11-05-2007

Entry Time: 23-09-2007 14:02:56

Modification Time: 24-12-2007 11:04:32

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 9

Document #: R158088013

CRF Status: Entry Complete

Approver:

Verifier:

Comment:

Section: Hdyf_Oral_Health	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 11-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:02:56	
		Last Modification Time: 27-11-2007 23:38:54	
		Page number: 24	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
1241	YES	ND	

Section: Vital	2 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 11-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:02:56	
		Last Modification Time: 23-09-2007 14:06:15	
		Page number: 24	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
1249	120	83	59
			Respiratory Rate
			12
			Temperature
			36.4
			xxx.x
			Unit
			C
Comments			

Section: Expired_Carbon_M	3 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 11-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:02:56	
		Last Modification Time: 23-09-2007 14:06:15	
		Page number: 24	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1253	20	03.8	

Section: Blood_Sampl_Cohb	4 of 6	Blank? N	Section Status: Entry Complete
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# CRF Report for Study E6270229

Patient: 5012  
CRF: Week 2  
Visit: WEEK 2

Site: CA\_001  
Blank? N  
Visit Date: 11-05-2007

Investigator: C2785\_03  
CRF Page #: 9  
Document #: R158088013

Section: Blood_Sampl_Cohb	4 of 6	Section Date: 11-05-2007
Visit: WEEK 2		Entry Time: 23-09-2007 14:02:56
Entered By: Ben Heyen		Last Modification Time: 23-09-2007 14:06:15
		Page number: 24

Blood Sampling for %COHb	
Actual Time	Comments
1256	

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 11-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:02:56	
		Last Modification Time: 27-11-2007 23:39:13	
		Page number: 25	

Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
ND	ND	Packs	Individual Cigarettes / pouches
		ND	ND

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 11-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:02:56	
		Last Modification Time: 20-12-2007 22:39:07	
		Page number: 25	

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1247	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 5012  
 CRF: Week 4  
 Visit: WEEK 4  
 Entered By: Ben Heyen  
 Discrepancies: Active  
 Approval Status: Not Approved  
 Verification: Not Verified  
 Comment:

Site: CA\_001  
 Blank? N  
 Visit Date: 25-05-2007  
 Entry Time: 23-09-2007 14:06:23  
 Modification Time: 24-12-2007 11:04:32  
 Approval Time:  
 Verification Time:

Investigator: C2785\_03  
 CRF Page #: 10  
 Document #: R158088213  
 CRF Status: Entry Complete  
 Approver:  
 Verifier:

Section: Pro_Questionnair	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 25-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:06:23	
		Last Modification Time: 20-11-2007 16:03:46	
		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  YES

Section: Hdyf_Oral_Health	2 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 25-05-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:06:23	
		Last Modification Time: 27-11-2007 23:39:28	
		Page number: 26	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY Oral Health Questions Performed?			
Actual Time	HDYF Performed?	Performed?	Comments
1228	YES	ND	

Section: Vital	3 of 6	Blank? N	Section Status: Entry Complete			
Visit: WEEK 4		Section Date: 25-05-2007				
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:06:23				
		Last Modification Time: 23-09-2007 14:22:43				
		Page number: 26				
VITAL SIGNS Blood Pressure Actual Time    Systolic    Diastolic    Pulse    Respiratory Rate    Oral Temperature    Unit						
1245	129	79	67	10	36.4	C
				xxx.x		
Comments						

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 4

Visit: WEEK 4

Site: CA\_001

Blank? N

Visit Date: 25-05-2007

Investigator: C2785\_03

CRF Page #: 10

Document #: R158088213

Section: Expired_Carbon_M	4 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 25-05-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 14:06:23	
		Last Modification Time: 23-09-2007 14:22:43	
		Page number: 26	

EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1248	47	08.1	

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 25-05-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 14:06:23	
		Last Modification Time: 20-11-2007 16:07:32	
		Page number: 27	

Unused Study Product Returned			
Product Returned	Flavor	Packs	Amount Returned
			Individual Cigarettes / pouches
ND	ND	ND	ND

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 25-05-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 14:06:23	
		Last Modification Time: 25-09-2007 22:47:59	
		Page number: 27	

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1250	SNUS	FROST	2

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 6

Visit: WEEK 6

Entered By: Ben Heven

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 06-06-2007

Entry Time: 23-09-2007 14:08:39

Modification Time: 27-11-2007 23:39:58

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 11

Document #: R158088613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 6		Section Date: 06-06-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 14:08:39	
		Last Modification Time: 27-11-2007 23:39:58	
		Page number: 28	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
1154	YES	ND	

Section: Expired_Carbon_M	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 6		Section Date: 06-06-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 14:08:39	
		Last Modification Time: 23-09-2007 14:25:02	
		Page number: 28	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1203	27	04.9	

Section: Vital	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 6		Section Date: 06-06-2007	
Entered By: Ben Heven		Entry Time: 23-09-2007 14:08:39	
		Last Modification Time: 23-09-2007 14:25:02	
		Page number: 28	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
1158	125	76	58
			Respiratory Rate
			14
			Temperature
			36.4
			xxx.x
Unit			
C			
Comments			

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

Patient: 5012  
CRF: Week 6  
Visit: WEEK 6

Site: CA\_001  
Blank? N  
Visit Date: 06-06-2007

Investigator: C2785\_03  
CRF Page #: 11  
Document #: R158088613

Section: Unused_Study_Pro	4 of 5		
Visit: WEEK 6		Section Date: 06-06-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:08:39	
		Last Modification Time: 20-11-2007 16:09:16	
		Page number: 29	

Unused Study Product Returned			
Product Returned	Flavor	Packs	Amount Returned Individual Cigarettes / pouches
ND	ND	ND	ND

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 6		Section Date: 06-06-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:08:39	
		Last Modification Time: 25-09-2007 22:48:31	
		Page number: 29	

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1215	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 5012  
 CRF: Week 8  
 Visit: WEEK 8  
 Entered By: Ben Heyen  
 Discrepancies: Active  
 Approval Status: Not Approved  
 Verification: Not Verified

Site: CA\_001  
 Blank? N  
 Visit Date: 19-06-2007  
 Entry Time: 23-09-2007 14:26:22  
 Modification Time: 27-11-2007 23:40:16  
 Approval Time:  
 Verification Time:

Investigator: C2785\_03  
 CRF Page #: 13  
 Document #: R158091313  
 CRF Status: Entry Complete

Approver:  
 Verifier:

## Comment:

Section: Pro_Questionnair	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 19-06-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:26:22	
		Last Modification Time: 23-09-2007 14:28:07	
		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  NO

Section: HDyf_Oral_Health	2 of 6	Blank? N	Section Status: Entry Complete								
Visit: WEEK 8		Section Date: 19-06-2007									
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:26:22									
		Last Modification Time: 27-11-2007 23:40:16									
		Page number: 30									
HDYF? / ORAL HEALTH QUESTIONS INQUIRY Oral Health Questions <table border="1"> <thead> <tr> <th>Actual Time</th> <th>HDYF Performed?</th> <th>Performed?</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>1218</td> <td>YES</td> <td>ND</td> <td></td> </tr> </tbody> </table>				Actual Time	HDYF Performed?	Performed?	Comments	1218	YES	ND	
Actual Time	HDYF Performed?	Performed?	Comments								
1218	YES	ND									

Section: Vital	3 of 6	Blank? N	Section Status: Entry Complete												
Visit: WEEK 8		Section Date: 19-06-2007													
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:26:22													
		Last Modification Time: 23-09-2007 14:28:07													
		Page number: 30													
VITAL SIGNS <table border="1"> <thead> <tr> <th>Actual Time</th> <th>Blood Pressure</th> <th>Pulse</th> <th>Respiratory Rate</th> <th>Oral Temperature</th> <th>Unit</th> </tr> </thead> <tbody> <tr> <td>1223</td> <td>Systolic 118 Diastolic 77</td> <td>58</td> <td>14</td> <td>36.9 xxx.x</td> <td>C</td> </tr> </tbody> </table>				Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit	1223	Systolic 118 Diastolic 77	58	14	36.9 xxx.x	C
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit										
1223	Systolic 118 Diastolic 77	58	14	36.9 xxx.x	C										
Comments															

# CRF Report for Study E6270229

Patient: 5012  
CRF: Week 8  
Visit: WEEK 8

Site: CA\_001  
Blank? N  
Visit Date: 19-06-2007

Investigator: C2785\_03  
CRF Page #: 13  
Document #: R158091313

Section: Expired_Carbon_M	4 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 19-06-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:26:22	
		Last Modification Time: 23-09-2007 14:28:07	
		Page number: 30	

EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1229	21	03.9	

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 19-06-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:26:22	
		Last Modification Time: 20-11-2007 16:22:41	
		Page number: 31	

Unused Study Product Returned			
Product Returned	Flavor	Packs	Individual Cigarettes / pouches
ND	ND	ND	ND

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 19-06-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:26:22	
		Last Modification Time: 25-09-2007 22:49:00	
		Page number: 31	

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1222	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 5012  
 CRF: Week 10  
 Visit: WEEK 10  
 Entered By: Ben Heyen  
 Discrepancies: Active  
 Approval Status: Not Approved  
 Verification: Not Verified

Site: CA\_001  
 Blank? N  
 Visit Date: 06-07-2007  
 Entry Time: 23-09-2007 14:28:10  
 Modification Time: 27-11-2007 23:40:33  
 Approval Time:  
 Verification Time:

Investigator: C2785\_03  
 CRF Page #: 14  
 Document #: R158091813  
 CRF Status: Entry Complete

Approver:  
 Verifier:

## Comment:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 06-07-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:28:10	
		Last Modification Time: 27-11-2007 23:40:33	
		Page number: 32	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
1150	YES	ND	

Section: Expired_Carbon_M	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 06-07-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:28:10	
		Last Modification Time: 23-09-2007 14:31:54	
		Page number: 32	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1158	31	05.5	

Section: Vital	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 06-07-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:28:10	
		Last Modification Time: 23-09-2007 14:31:54	
		Page number: 32	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
1156	116	71	68
			Respiratory Rate
			14
			Temperature
			36.1
			xxx.x
Unit			
C			
Comments			

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

Patient: 5012

CRF: Week 10

Visit: WEEK 10

Site: CA\_001

Blank? N

Visit Date: 06-07-2007

Investigator: C2785\_03

CRF Page #: 14

Document #: R158091813

Section: Unused_Study_Pro	4 of 5	Section Date: 06-07-2007
Visit: WEEK 10		Entry Time: 23-09-2007 14:28:10
Entered By: Ben Heyen		Last Modification Time: 20-11-2007 16:46:53
		Page number: 33
Unused Study Product Returned		
Product Returned	Flavor	Amount Returned
Packs	Individual Cigarettes / pouches	
ND	ND	ND

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 06-07-2007	
Entered By: Ben Heyen		Entry Time: 23-09-2007 14:28:10	
		Last Modification Time: 20-11-2007 16:50:11	
		Page number: 33	
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1156	SNUS	FROST	1

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 12

Visit: WEEK 12

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Entry Time: 20-11-2007 17:05:38

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 15

Document #: R167086313

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:38	
		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: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:38	
		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: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:38	
		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: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:38	
		Last Modification Time:	
		Page number: 34	
Pregnancy Test			

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 12

Visit: WEEK 12

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Investigator: C2785\_03

CRF Page #: 15

Document #: R167086313

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 20-11-2007 17:05:38	
Entered By: Ben Heven	Last Modification Time:	Page number: 34	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
			Comments

Section: Hdyl_Oral_Health	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 20-11-2007 17:05:38	
Entered By: Ben Heven	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: 00-00-	Entry Time: 20-11-2007 17:05:38	
Entered By: Ben Heven	Last Modification Time:	Page number: 35	
VITAL SIGNS			
	Blood Pressure		Oral
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
			Temperature
			Unit
			xxx.x
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 20-11-2007 17:05:38	
Entered By: Ben Heven	Last Modification Time:	Page number: 35	
ORAL HEALTH EXAMINATION			

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 12

Visit: WEEK 12

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Investigator: C2785\_03

CRF Page #: 15

Document #: R167086313

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: 00-00-	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:05:38	
		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: 00-00-	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:05:38	
		Last Modification Time:	
		Page number: 36	
WEIGHT & HEIGHT			
Date	Weight	Unit	Height
	xxx.x		xxx.x

Section: Lab_Eval	11 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:05:38	
		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: 5012

CRF: Week 12(2)

Visit: WEEK 12

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Entry Time: 20-11-2007 17:05:43

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 16

Document #: R167086413

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:43	
		Last Modification Time:	
		Page number: 37	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:43	
		Last Modification Time:	
		Page number: 37	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
			Comments

Section: Blood_Sampl_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:43	
		Last Modification Time:	
		Page number: 37	
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:43	
		Last Modification Time:	
		Page number: 38	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
	Actual Time		

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 12(2)

Visit: WEEK 12

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Investigator: C2785\_03

CRF Page #: 16

Document #: R167086413

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

Section: Proventil_Admin	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:43	
	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: 00-00-		Entry Time: 20-11-2007 17:05:43				
Entered By: Ben Heven	Last Modification Time:		Page number: 38				
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
Date	Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments

Section: Used Study Tobac		7 of 11		Blank? Y		Section Status: Created			
Visit: WEEK 12				Section Date: 00-00-					
Entered By: Ben Heven				Entry Time: 20-11-2007 17:05:43					
				Last Modification Time:					
				Page number: 39					
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
Scheduled Collection				Number of Study					
				Tobacco-Heating					
						Weight of			
				Cigarettes		Cigarettes Collected		Any Product	
				Collected		(g)		Deviation?	
								If yes, # of other	
								Brand	
								Comments	

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:05:43	

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 12(2)

Visit: WEEK 12

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Investigator: C2785\_03

CRF Page #: 16

Document #: R167086413

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: 00-00-

Entry Time: 20-11-2007 17:05:43

Entered By: Ben Heyen

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: 00-00-

Entry Time: 20-11-2007 17:05:43

Entered By: Ben Heyen

Last Modification Time:

Page number: 42

## 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 12

Section Date: 00-00-

Entry Time: 20-11-2007 17:05:43

Entered By: Ben Heyen

Last Modification Time:

Page number: 43

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 12(3)

Visit: WEEK 12

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Entry Time: 20-11-2007 17:05:48

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 17

Document #: R167086513

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:48	
		Last Modification Time:	
		Page number: 44	
Unused Study Product Returned			
			Amount Returned
Date	Actual Time	Product Returned	Packs Individual Cigarettes / pouches

Section: Study_Prod_Dispe		2 of 2	Blank? Y		Section Status: Created	
Visit: WEEK 12		Section Date: 00-00-				
Entered By: Ben Heven		Entry Time: 20-11-2007 17:05:48				
		Last Modification Time:				
		Page number: 44				
STUDY PRODUCT DISPENSATION						
Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed		



# CRF Report for Study E6270229

Patient: 5012

CRF: Week 14

Visit: WEEK 14

Entered By: Ben Heyen

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Entry Time: 20-11-2007 17:06:42

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 18

Document #: R167086713

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:06:42	
		Last Modification Time:	
		Page number: 45	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:06:42	
		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: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:06:42	
		Last Modification Time:	
		Page number: 45	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:06:42	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 14

Visit: WEEK 14

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 18

Document #: R167086713

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: 31-07-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 17:06:42

Last Modification Time:

Page number: 46

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 16

Visit: WEEK 16

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Entry Time: 20-11-2007 17:07:15

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 19

Document #: R167086913

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:15	
		Last Modification Time:	
		Page number: 47	
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:15	
		Last Modification Time:	
		Page number: 47	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:15	
		Last Modification Time:	
		Page number: 47	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 31-07-2007	

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 16

Visit: WEEK 16

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 19

Document #: R167086913

Section: Expired\_Carbon\_M 4 of 6

Entered By: Ben Heyen

Entry Time: 20-11-2007 17:07:15

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: 31-07-2007

Entry Time: 20-11-2007 17:07:15

Entered By: Ben Heyen

Last Modification Time:

Page number: 48

## Unused Study Product Returned

Product Returned	Flavor	Packs	Amount Returned	Individual Cigarettes / pouches
------------------	--------	-------	-----------------	---------------------------------

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 31-07-2007

Entry Time: 20-11-2007 17:07:15

Entered By: Ben Heyen

Last Modification Time:

Page number: 48

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 18

Visit: WEEK 18

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Entry Time: 20-11-2007 17:07:26

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 20

Document #: R167087013

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:26	
		Last Modification Time:	
		Page number: 49	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health	
		Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:26	
		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: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:26	
		Last Modification Time:	
		Page number: 49	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
			Respiratory Rate
			Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:26	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 18

Visit: WEEK 18

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 20

Document #: R167087013

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: 31-07-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 17:07:26

Last Modification Time:

Page number: 50

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 20

Visit: WEEK 20

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Entry Time: 20-11-2007 17:07:56

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 21

Document #: R167087213

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:56	
		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: Hdvf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:56	
		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: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:07:56	
		Last Modification Time:	
		Page number: 51	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Temperature
			xxx.x
Unit			
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 31-07-2007	

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 20

Visit: WEEK 20

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 21

Document #: R167087213

Section: Expired\_Carbon\_M 4 of 6

Entered By: Ben Heyen

Entry Time: 20-11-2007 17:07:56

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: 31-07-2007

Entry Time: 20-11-2007 17:07:56

Entered By: Ben Heyen

Last Modification Time:

Page number: 52

## Unused Study Product Returned

Product Returned	Flavor	Packs	Amount Returned	Individual Cigarettes / pouches
------------------	--------	-------	-----------------	---------------------------------

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 31-07-2007

Entry Time: 20-11-2007 17:07:56

Entered By: Ben Heyen

Last Modification Time:

Page number: 52

## STUDY PRODUCT DISPENSATION

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



# CRF Report for Study E6270229

Patient: 5012

CRF: Week 22

Visit: WEEK 22

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Entry Time: 20-11-2007 17:08:07

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 22

Document #: R167087313

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:08:07	
		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: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:08:07	
		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: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:08:07	
		Last Modification Time:	
		Page number: 53	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		xxx.x	
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:08:07	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 22

Visit: WEEK 22

Site: CA\_001

Blank? Y

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 22

Document #: R167087313

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: 31-07-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 17:08:07

Last Modification Time:

Page number: 54

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Ben Heyen

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 31-07-2007

Entry Time: 20-11-2007 17:25:47

Modification Time: 24-12-2007 11:04:32

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 23

Document #: R167087613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:25:47	
		Last Modification Time: 20-11-2007 17:38:35	
		Page number: 55	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject	YES / NO	
31-07-2007	complete Smoker Routine Questionnaire PRIOR to any		
	study procedures being performed?	YES	

Section: Urine_Drug	2 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:25:47	
		Last Modification Time: 20-12-2007 22:46:23	
		Page number: 55	
Drug Screen			
Date	Drug Screen Result		
ND	ND		

Section: Alcohol_Screen	3 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:25:47	
		Last Modification Time: 20-12-2007 22:46:23	
		Page number: 55	
Alcohol Screen			
Date	Breathalyzer Result		
09-08-2007	NEG		

Section: Preg_Test	4 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:25:47	
		Last Modification Time: 20-12-2007 22:46:23	
		Page number: 55	

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CA\_001

Blank? N

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 23

Document #: R167087613

Section: Preg\_Test

4 of 12

Pregnancy Test

Date

Result

NA

N/A,

MALE

OR

FEMA

LE

Section: Urine\_Coll

5 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-11-2007 17:38:35

Page number: 55

24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	31-07-2007	1409	NA	NA	NA	
0 HOUR TO 24 HOURS	ND	ND	ND	ND	ND	

Section: ECG

6 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-12-2007 22:46:23

Page number: 56

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

1445

56

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

214

88

378

365

ECG INTERPRETATION:

ANCS

Comments (related to abnormal, CS findings only):

Section: Hdvf\_Oral\_Health

7 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-11-2007 17:38:35

Page number: 57

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CA\_001

Blank? N

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 23

Document #: R167087613

Section: Hdyl\_Oral\_Health 7 of 12

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Date	Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
31-07-2007	0932	YES	YES	

Section: Vital

8 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-11-2007 17:38:35

Page number: 57

## VITAL SIGNS

Date	Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral	Unit
		Systolic	Diastolic			Temperature	
31-07-2007	0848	114	76	64	18	36.4 xxx.x	C

Comments

Section: Oral\_Health\_Exam

9 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-11-2007 17:48:14

Page number: 57

## ORAL HEALTH EXAMINATION

Date	Procedure	Relevant Findings?*	Findings
31-07-2007	ORAL HEALTH QUESTIONS PERFORMED	NO	
31-07-2007	EVIDENCE OF LEUKOPLAKIA	NO	
	OTHER ORAL KERATOSIS	NO	

Section: Phys\_Exam

10 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-11-2007 17:48:14

Page number: 58

## PHYSICAL EXAMINATION

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CA\_001

Blank? N

Visit Date: 31-07-2007

Investigator: C2785\_03

CRF Page #: 23

Document #: R167087613

Section: Phys\_Exam

10 of 12

Date  
31-07-2007

Code Number	Code	Relevant Findings?	Findings
01	GENERAL	NO	
02	SKIN	NO	
03	HEENT	NO	
04	MOUTH	NO	
05	NECK	NO	
06	THORAX/LUNG	NO	
07	CARDIO	NO	
08	ABDOMEN	NO	
09	MUSCULO	NO	
10	NEURO	NO	
11	LYMPH	NO	
12	OTHER	NA	

Section: Weight\_Height

11 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-11-2007 17:48:14

Page number: 58

Date	WEIGHT & HEIGHT	Weight	Unit	Height	Unit
31-07-2007		70.5	KG	NA	
		xxx.x		xxx.x	

Section: Lab\_Eval

12 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 17:25:47

Last Modification Time: 20-12-2007 22:46:23

Page number: 59

## Laboratory Evaluations

Date	31-07-2007
Were the scheduled laboratory samples obtained?	YES No, specify
Requisition Number 1	N528417
Requisition Number 2 (if applicable)	
Were there any clinically significant labs?	NO (Yes, specify below)
Requisition Number	Test Name H/L Lab ID Lab Name

# CRF Report for Study E6270229



Patient: 5012

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Ben Heven

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 31-07-2007

Entry Time: 20-11-2007 17:54:18

Modification Time: 21-11-2007 12:19:38

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 24

Document #: R167091013

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:54:18	
		Last Modification Time: 20-11-2007 19:19:40	
		Page number: 59	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
31-07-2007	0901		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:54:18	
		Last Modification Time: 20-11-2007 19:19:40	
		Page number: 59	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
31-07-2007	1420	14	02.8

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:54:18	
		Last Modification Time: 20-11-2007 19:19:40	
		Page number: 59	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
31-07-2007	0901		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:54:18	
		Last Modification Time: 20-11-2007 19:19:40	
		Page number: 60	

# CRF Report for Study E6270229

Patient: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24-2 (Eos)

Blank? N

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 31-07-2007

Document #: R167091013

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time		Testing		FVC			
of FEV1/FVC		Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
Date	Test						
09-08-2007	1427	STANDI	3.57	93	4.73	102	
		NG					

Section: Proventil_Admin	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007	
Entered By: Ben Heven		Entry Time: 20-11-2007 17:54:18	
		Last Modification Time: 20-11-2007 19:19:40	
		Page number: 60	
PROVENTIL ADMINISTRATION			
	Actual Time of Proventil Administration	Amount Administered	Comments
Date			
31-07-2007	ND	NA	

Section: Post_Bronch_Spir		6 of 11		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007		Entry Time: 20-11-2007 17:54:18			
Entered By: Ben Heyen		Last Modification Time: 20-11-2007 19:19:40		Page number: 60			
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
Actual Time of FEV1/FVC		Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						
09-08-2007	ND	ND	ND	ND	ND	ND	

Section: Used_Study_Tobac	7 of 11	Blank? Y	Section Status: Created			
Visit: WEEK 24 (EOS)		Section Date: 31-07-2007				
Entered By: Ben Heyen		Entry Time: 20-11-2007 17:54:18				
		Last Modification Time: 20-11-2007 19:19:40				
		Page number: 61				
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION						
			Number of Study Tobacco-Heating Cigarettes	Weight of Cigarettes Collected	Any Product	If yes, # of other
Scheduled Collection	Stop	Stop				



# CRF Report for Study E6270229

Patient: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24-2 (Eos)

Blank? N

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 31-07-2007

Document #: R167091013

Section: Used_Study_Tobac		7 of 11							
Timepoint	Start Date	Start Time	Date	Time	Collected	(g)	Deviation?	Brand	Comments
24 HOURS PRIOR TO CHECK-IN	ND	ND	ND	ND	NA	NA	NA	NA	
24 HOURS IN-HOUSE	ND	ND	ND	ND	NA	NA	NA	NA	

Section: Used_Study_Snus		8 of 11		Blank? N		Section Status: Entry Complete			
Visit: WEEK 24 (EOS)				Section Date: 31-07-2007					
Entered By: Ben Heven				Entry Time: 20-11-2007 17:54:18					
				Last Modification Time: 20-11-2007 19:19:40					
				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
	24 HOURS PRIOR TO CHECK-IN	ND	ND	ND	ND	NA	NA	NA	
	24 HOURS IN-HOUSE	ND	ND	ND	ND	NA	NA	NA	

Section: Used_Study_Bum		9 of 11		Blank? Y		Section Status: Created			
Visit: WEEK 24 (EOS)				Section Date: 31-07-2007					
Entered By: Ben Heven				Entry Time: 20-11-2007 17:54:18					
				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: 31-07-2007					
Entered By: Ben Heven				Entry Time: 20-11-2007 17:54:18					
				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			
---------------------------	--	----------	--	----------	--	-------------------------	--	--	--

# CRF Report for Study E6270229



Patient: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Week 24-2 (Eos)

Blank? N

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 31-07-2007

Document #: R167091013

Section: Used\_Butt\_Measur 11 of 11

Visit: WEEK 24 (EOS)

Section Date: 31-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 17:54:18

Last Modification Time:

Page number: 65

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date

Period

Cigarette Butt Number

Cigarette Butt Measurement (mm)

# CRF Report for Study E6270229

Patient: 5012

CRF: Week 24-3

Visit: WEEK 24 (EOS)

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 00-00-

Entry Time: 20-11-2007 19:20:25

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 25

Document #: R167093613

CRF Status: Created

Approver:

Verifier:

Section: Unused Study Pro

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 00-00-

Entered By: Ben Heven

Entry Time: 20-11-2007 19:20:25

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: 5012

CRF: Precon\_Med

Visit: PRECON\_MEDS

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 09-08-2007

Entry Time: 20-11-2007 19:20:29

Modification Time: 20-11-2007 19:21:06

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 26

Document #: R167093713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pre\_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON\_MEDS

Section Date: 09-08-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 19:20:29

Last Modification Time: 20-11-2007 19:21:06

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: 5012

CRF: AE

Visit: AE

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 09-08-2007

Entry Time: 20-11-2007 19:21:14

Modification Time: 20-11-2007 19:35:57

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 27

Document #: R167093913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ae\_Med

Blank? N

Section Status: Entry Complete

Visit: AE

Section Date: 09-08-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 19:21:14

Last Modification Time: 20-11-2007 19:35:57

Page number: 67

## Adverse Events

Did the subject experience any adverse events?

NO

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

# CRF Report for Study E6270229

Patient: 5012

CRF: Ecg\_Unscheduled

Visit: ECG\_UNSCHE

Entered By: Ben Heyen

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 09-08-2007

Entry Time: 20-11-2007 19:35:58

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 28

Document #: R167094013

CRF Status: Created

Approver:

Verifier:

Section: ECG

Blank? Y

Section Status: Created

Visit: ECG\_UNSCHE

Section Date: 09-08-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 19:35:58

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: 5012

CRF: Lab\_Unscheduled

Visit: LAB\_UNSCHE

Entered By: Ben Heven

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 27-04-2007

Entry Time: 20-11-2007 14:34:32

Modification Time: 21-11-2007 12:19:38

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 29

Document #: R167062313

CRF Status: Entry Complete

Approver:

Verifier:

Section: Lab\_Eval

Blank? N

Section Status: Entry Complete

Visit: LAB\_UNSCHE

Section Date: 27-04-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 14:34:32

Last Modification Time: 20-11-2007 14:36:42

Page number: 69

## Unscheduled Laboratory Evaluations

Date	Requisition Number	Clinically Significant?	Test Name	If Clinically Significant, Specify High(H)/Low(L)	Lab ID	Lab Name	Comments
27-04-2007	O062495	NO	URINE MACRO AND MICRO PANEL			COVANCE CLS	

# CRF Report for Study E6270229

Patient: 5012

CRF: Vital\_Unscheduled

Visit: VITAL\_UNSCHEDED

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 09-08-2007

Entry Time: 20-11-2007 19:36:16

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 30

Document #: R167094113

CRF Status: Created

Approver:

Verifier:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL\_UNSCHEDED

Section Date: 09-08-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 19:36:16

Last Modification Time:

Page number: 70

## UNSCHEDULED VITAL SIGNS

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



# CRF Report for Study E6270229

Patient: 5012

CRF: StdY\_Prdt\_Dis\_Unscheduled

Visit: STDY\_PRDT\_UNSCHE

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 09-08-2007

Entry Time: 20-11-2007 19:36:26

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 31

Document #: R167094213

CRF Status: Created

Approver:

Verifier:

Section: Study\_Prod\_Dispe

Blank? Y

Section Status: Created

Visit: STDY\_PRDT\_UNSCHE

Section Date: 09-08-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 19:36:26

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: 5012

CRF: Expired\_Co2\_Unscheduled

Visit: EXPIRED\_CO2\_UNSC

Entered By: Ben Heyen

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 09-08-2007

Entry Time: 20-11-2007 19:36:37

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 32

Document #: R167094313

CRF Status: Created

Approver:

Verifier:

Section: Expired\_Carbon\_M

Blank? Y

Section Status: Created

Visit: EXPIRED\_CO2\_UNSC

Section Date: 09-08-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 19:36:37

Last Modification Time:

Page number: 72

## UNSCHEDULED EXPIRED CARBON MONOXIDE

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

# CRF Report for Study E6270229

Patient: 5012

CRF: Oral\_Health\_Unscheduled

Visit: ORAL\_HEALTH\_UNSC

Entered By: Ben Heyen

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? Y

Visit Date: 09-08-2007

Entry Time: 20-11-2007 19:36:44

Modification Time:

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 33

Document #: R167094413

CRF Status: Created

Approver:

Verifier:

Section: Oral\_Health\_Exam

Blank? Y

Section Status: Created

Visit: ORAL\_HEALTH\_UNSC

Section Date: 09-08-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 19:36:44

Last Modification Time:

Page number: 73

## UNSCHEDULED ORAL HEALTH EXAMINATION

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

# CRF Report for Study E6270229

Patient: 5012

Site: CA\_001

Investigator: C2785\_03

CRF: Spirometry\_Unscheduled

Blank? Y

CRF Page #: 34

Visit: SPIRO\_TEST\_UNSCH

Visit Date: 16-07-2007

Document #: R167094613

Entered By: Ben Heyen

Entry Time: 20-11-2007 19:37:01

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pre\_Bronch\_Spir

Blank? Y

Section Status: Created

Visit: SPIRO\_TEST\_UNSCH

Section Date: 16-07-2007

Entered By: Ben Heyen

Entry Time: 20-11-2007 19:37:01

Last Modification Time:

Page number: 74

## UNSCHEDULED SPIROMETRY TEST RESULT

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

# CRF Report for Study E6270229

Patient: 5012

CRF: Study\_Completion

Visit: STUDY\_COMP

Entered By: Ben Heven

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CA\_001

Blank? N

Visit Date: 16-07-2007

Entry Time: 20-11-2007 19:37:09

Modification Time: 20-11-2007 19:37:54

Approval Time:

Verification Time:

Investigator: C2785\_03

CRF Page #: 35

Document #: R167094713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study\_Comp

Blank? N

Section Status: Entry Complete

Visit: STUDY\_COMP

Section Date: 16-07-2007

Entered By: Ben Heven

Entry Time: 20-11-2007 19:37:09

Last Modification Time: 20-11-2007 19:37:54

Page number: 75

## Study Completion

Did the subject complete the study?

NO

Date the subject completed OR withdrew from the study:

31-07-2007

Reason for Withdrawal

CONSENT

Specify

Investigator Comments

Principal Investigator

*W. Cantor*

Date

*26 Dec 2007*

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0482306

Page 1 of 2

## 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: 1

## SPONSOR REPORT TO:

Russell M. Dixon, MD  
Medical Director  
Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

Screen

COLLECTION TIME: 08:17 DATE: 04-Apr-2007

DATE RECEIVED IN LABORATORY: 05-Apr-2007

DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6)

AGE: 33

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

## CHEMISTRY PANEL

Total Bili	0.4	0.2-1.2 mg/dL
Alk Phos	73	31-129 U/L
ALT (SGPT)	14	6-43 U/L
AST (SGOT)	19	11-36 U/L
GGT	28	10-61 U/L
LDH	168	53-234 U/L
Urea Nitr	13	4-24 mg/dL
Creatinine	1.4	0.5-1.2 mg/dL
Glucose	83	70-115 mg/dL
Uric Acid	5.9	2.1-8.2 mg/dL
Calcium	9.9	8.3-10.6 mg/dL
Phosphorus	4.0	2.2-5.1 mg/dL
Total Prot	7.6	6.1-8.4 g/dL
Albumin	4.5	3.3-4.9 g/dL
Sodium	141	132-147 mEq/L
Potassium	4.3	3.4-5.4 mEq/L
Chloride	105	94-112 mEq/L

[ ]

[X]

  
Investigator Signature:

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

QC'd  
by  
Mues  
20 Apr  
2007

09 Apr 07  
Date:

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. 0482306

Page 2 of 2

## 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: 1

## SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 08:17 DATE: 04-Apr-2007

DATE RECEIVED IN LABORATORY: 05-Apr-2007

DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 33

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

## HEMATOLOGY&amp; DIFFERENTIAL PANEL

HGB	15.1	12.7-18.1 g/dL
HCT	43	39-54 %
RBC	4.7	4.5-6.4x10 <sup>6</sup> /uL
MCV	92	79-96 fL
MCH	32	26-34 pg
MCHC	35	31-38 g/dL
RDW	13.9	12.0-15.0 %
RBC Morph	Normocytic	
WBC	9.02	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	4.99	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	3.57	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.29	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.14	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.04	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	55.3	40.5-75.0 %
Lymphocyte	39.6	15.4-48.5 %
Monocytes	3.2	2.6-10.1 %
Eosinophil	1.5	0.0-6.8 %
Basophils	0.4	0.0-2.0 %
Platelets	237	140-400 x10 <sup>3</sup> /uL

URINE MACRO &amp; MICRO PANEL - See Note #1

Note #1 - Quantity not sufficient

Investigator Signature: 

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

QC'd

by

Ales

20 Apr

2007

09 Apr 07

Date:

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. 0482306

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: 08:17 DATE: 04-Apr-2007

DATE RECEIVED IN LABORATORY: 05-Apr-2007

DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 33

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

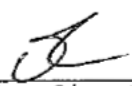
## TOTAL IRON

Total Iron 56 45-160 ug/dL

## HEPATITIS A ANTIBODY-IGM

HepA IgMab Negative No Ref Rng

QC'd  
by  
CLS  
20 Apr  
2007

  
Investigator Signature:

04 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)



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

**LABORATORY REPORT**

ACCESSION NO. 0482306

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: 1

## SPONSOR REPORT TO:

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

Screen

COLLECTION TIME: 08:17 DATE: 04-Apr-2007

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DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 33

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEPATITIS B SURFACE ANTIGEN

HBSAG Negative No Ref Rng

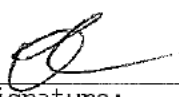
## HEPATITIS C VIRUS ANTIBODY

ANTI-HCV Negative No Ref Rng

## HEPATITIS B SURFACE ANTIBODY

HBSAB Negative No Ref Rng

QC'd  
by  
AUS  
20 Apr  
2007

  
Investigator Signature:

09 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

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(INV)

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

ACCESSION NO. 0482306

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

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DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 33

SCREENING NUMBER: S5042


Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HIV 1/HIV 2 ANTIBODY SCREEN**

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

  
Investigator Signature:

09 Apr 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 T-Telephoned P-"Panic" EX-Exclusions 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. 0482306

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: 1

SPONSOR REPORT TO:

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

Screen

COLLECTION TIME:08:17 DATE:04-Apr-2007

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DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 33

SCREENING NUMBER: S5042

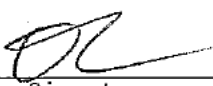
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng:Negative

  
Investigator Signature:

QC'd  
by  
AUS  
20 Apr  
2007

09 Apr 07  
Date:

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

B17181

(INV)

**Covance CLS**

Marietta Henry, M.D., Director  
8241 SciCor Drive - Indianapolis, IN 46214-2985  
Tel. #1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. 0482306

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: 08:17 DATE: 04-Apr-2007

DATE RECEIVED IN LABORATORY: 05-Apr-2007

DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 33

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

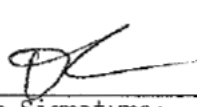
Fasted?

Yes

IS SUBJECT A SMOKER OR NON-SM?

smoker/non

Smoker

  
Investigator Signature:

09 Apr 07  
Date:

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. 0478659

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: 1

## SPONSOR REPORT TO:

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

## Retest

COLLECTION TIME: 08:08 DATE: 12-Apr-2007  
DATE RECEIVED IN LABORATORY: 13-Apr-2007  
DATE REPORTED BY LABORATORY: 17-Apr-2007  
SEX: M BIRTHDATE: (b) (6) AGE: 34  
SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?  
Yes No

## URINE MACRO &amp; MICRO PANEL

Color	Colorless	Ref Rng:
Clarity	Clear	Colorless or Yellow
Spec Grav	1.003	Ref Rng: Clear
pH	5.0	1.003-1.035
Protein	Negative	5.0-8.0
Glucose	Normal	Ref Rng: Negative
Ketones	Negative	Ref Rng: Normal
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Negative
Blood	Negative	Ref Rng: Normal
Nitrite	Negative	Ref Rng: Negative
Leuk Est	+1 H	Ref Rng: Negative
Microscop	Positive	

[ ] [x]

## CELLULAR ELEMENTS

WBC	6	H	0-5 /HPF
-----	---	---	----------

[ ] [x]

4/24/07  
repeat  
dipstick/micro

*Russell M. Dixon*  
Investigator Signature:

QC'd  
ALLS  
20 APR  
2007

04/24/07  
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. 0478659

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

Retest

COLLECTION TIME: 08:08 DATE: 12-Apr-2007

DATE RECEIVED IN LABORATORY: 13-Apr-2007

DATE REPORTED BY LABORATORY: 17-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
 Significant/ Adverse  
 Event?

Yes No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

IS SUBJECT A SMOKER OR NON-SM?

smoker/non Smoker

QC'd  
 by  
 AUS  
 20 Apr  
 2007

*Linda Burdick*  
 Investigator Signature:

04/24/07  
 Date:

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. 0958598

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: R5012

PATIENT INITIALS: (b) (6)

VISIT: 4

Week 2

COLLECTION TIME: 12:56 DATE: 11-May-2007

DATE RECEIVED IN LABORATORY: 12-May-2007

DATE REPORTED BY LABORATORY: 12-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

CARBOXYHEMOGLOBIN

Carboxyhem 4.2

% saturation

No Ref Rng

  
Investigator Signature:

16 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**

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

ACCESSION NO. N528417

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: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 09:01 DATE: 31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 08-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes


No

sICAM-1

sICAM-1

185

115-306 ng/mL

  
Investigator Signature:

09 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**

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

**LABORATORY REPORT**

ACCESSION NO. N528417

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: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME:09:01 DATE:31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 03-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

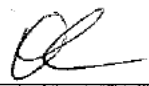
SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

**FIBRINOGEN**

Fibrinogen 259 200-400 mg/dL

  
Investigator Signature:

09 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)

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**LABORATORY REPORT**

ACCESSION NO. N528417

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: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 09:01 DATE: 31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 03-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL IRON


Total Iron 77 45-160 ug/dL

## C-REACTIVE PROTEIN

CRP-HS 0.081 <=0.287 mg/dL

## CARBOXYHEMOGLOBIN

Carboxyhem 4.9 % saturation  
No Ref Rng

  
Investigator Signature:

09 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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Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. N528417

Page 1 of 2

## 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  
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3402 Kinsman Boulevard  
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME:09:01 DATE:31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 02-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042


Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## CHEMISTRY PANEL

Total Bili	0.5	0.2-1.2 mg/dL
Alk Phos	66	31-129 U/L
ALT (SGPT)	20	6-43 U/L
AST (SGOT)	23	11-36 U/L
GGT	28	10-61 U/L
LDH	169	53-234 U/L
Urea Nitr	8	4-24 mg/dL
Creatinine	1.2	0.5-1.2 mg/dL
Glucose	83	70-115 mg/dL
Uric Acid	5.9	2.1-8.2 mg/dL
Calcium	9.7	8.3-10.6 mg/dL
Phosphorus	3.1	2.2-5.1 mg/dL
Total Prot	7.4	6.1-8.4 g/dL
Albumin	4.5	3.3-4.9 g/dL
Sodium	142	132-147 mEq/L
Potassium	4.5	3.4-5.4 mEq/L
Chloride	103	94-112 mEq/L

  
Investigator Signature:

09 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)

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**LABORATORY REPORT**

ACCESSION NO. N528417

Page 2 of 2

**INVESTIGATOR: (B17181)**

David Carter, M.D.  
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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: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 09:01 DATE: 31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 02-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

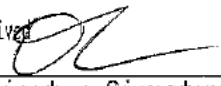
No

**HEMATOLOGY& DIFFERENTIAL PANEL**

HGB	15.2	12.7-18.1 g/dL
HCT	42	39-54 %
RBC	4.7	4.5-6.4x10 <sup>6</sup> /uL
MCV	91	79-96 fL
MCH	33	26-34 pg
MCHC	36	31-38 g/dL
RDW	14.6	12.0-15.0 %
RBC Morph	Normocytic	
WBC	5.65	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	2.87	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.45	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.21	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.06	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.06	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	50.8	40.5-75.0 %
Lymphocyte	43.5	15.4-48.5%
Monocytes	3.6	2.6-10.1 %
Eosinophil	1.1	0.0-6.8 %
Basophils	1.1	0.0-2.0 %
Platelets	223	140-400 x10 <sup>3</sup> /uL

URINE MACRO &amp; MICRO PANEL - See Note #1

Note #1 - No specimen received

Investigator Signature: 09 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**

Marietta Henry, M.D., Director  
9211 SciCor Drive - Indianapolis, IN 46214-2985  
Tel. +1 (800) 327 7270

**LABORATORY REPORT**

ACCESSION NO. N528417

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: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 09:01 DATE: 31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 02-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No


**HOMOCYSTEINE**

\*1 HCY 43.19 H 5.90-16.00 umol/L

[ ]

[✓]

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

  
Investigator Signature:

09 Aug 07  
Date:

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SCREENING NUMBER: S5042

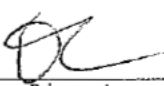
Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

URINE CREATININE, SPOT - See Note #1

Note #1 - No specimen received

  
Investigator Signature:09 Aug 07  
Date

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SCREENING NUMBER: S5042


Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

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

Note #1 - Specimen received beyond stability

  
Investigator Signature:

09 Aug 07  
Date:

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INVESTIGATOR NO.: 5

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DATE REPORTED BY LABORATORY: 02-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34


SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

HAS PATIENT FASTED 8 HOURS?

Fasted? Yes

  
Investigator Signature:

09 Aug 07  
Date:

B17181

(INV)



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INVESTIGATOR NO.: 5

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEMOGLOBIN A1C**


Hgb A1c 5.1

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

  
Investigator Signature:  
Date:

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Madison, WI United States 53704

PROTOCOL : 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME:09:01 DATE:31-Jul-2007

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DATE REPORTED BY LABORATORY: 02-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

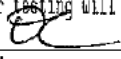
Is this Clinically  
Significant/ Adverse  
Event?

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:

  
Date:

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

B17181

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

(INV)

LOCATION:Covance CLS

RX TIME 08/02 '07 23:48

**Covance CLS**

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**LABORATORY REPORT**

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Austin, TX 78752

PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

## SPONSOR REPORT TO:

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

Week 24/Early Term

COLLECTION TIME: 09:01 DATE: 31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 12-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34


SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

## URINE MACRO &amp; MICRO PANEL

Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.010	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	Negative	

  
Investigator Signature:

17 Aug 07  
Date:

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SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?


Yes

No

**URINE CREATININE, SPOT**

Rnd Ur Crt 104

mg/dL No Ref Rng

  
Investigator Signature:

17 Aug 07  
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 5

RANDOMIZATION NUMBER: R5012

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 09:01 DATE: 31-Jul-2007

DATE RECEIVED IN LABORATORY: 01-Aug-2007

DATE REPORTED BY LABORATORY: 10-Aug-2007

SEX: M BIRTHDATE: (b) (6) AGE: 34

SCREENING NUMBER: S5042

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

LIPID PANEL - See Note #1

Note #1 - Specimen received beyond stability

*a*  
Investigator Signature:

*17 Aug 07*  
Date:

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B17181

(INV)

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