

# CRF Report for Study E6270229

Report run by Sharon Ladenes at 11-01-2008 17:42:55

## Report Parameters

Site: CD\_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: 2008

Ending patient: 2008

## Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc 123</b>

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

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

Page ID: D11765313

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Dallas  
Investigator: Patricia Chandler  
Date: 19-MAR-2008

Patient#: 2008  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Unused Study Product Returned WEEK 24 (EOS) Disc ID: 1355856313 Type: MANUAL	25 25APR07 Closed: N	Disc ID 1346090513 requested the number of 'Packs' returned for noted SNUS flavors. Resolution responses appear to be number of 'Pouched'. Please provide number of 'Packs'.	Original= <u>20</u> packs Frost= <u>20</u> packs Spice= <u>20</u> packs

Am2  
03/21/08

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

Date

## Data Clarification Form

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

Patient#: 2008  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Laboratory Evaluation WEEK 0 (BASELINE) Disc ID: 1346045213 Type: MANUAL	5 18APR07 Closed: N	Please confirm the following updates to the CS? analytes fields to correctly present the clinically significant analyte.	<input checked="" type="checkbox"/> Test Name: GLucose Lab ID: C01 Lab Name: CCLS [ ] Other: _____
Medical History SCREENING Disc ID: 1346038213 Type: MANUAL	3 21MAR07 Closed: N	1-Depression is currently noted with system Neurological. Please verify if this finding is best associated with system Psychological. 2-System Other appears to have been deleted from the MedHX page. Please confirm that all systems should be presented.	1- <input checked="" type="checkbox"/> Psychological [ ] Neurological [ ] Other: _____ 2- <input checked="" type="checkbox"/> Add 'Other' System No findings [ ] Add 'Other' System Finding= _____ Onset date= _____ Resolved date= _____

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

\_\_\_\_\_  
Authorized Personnel Signature

11 MAR 2008

Date

## Data Clarification Form

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

Patient#: 2008  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Medical History SCREENING Disc ID: 1346038713 Type: MANUAL	3 21MAR07 Closed: N	As these conditions resolved prior to Screening, and leading question indicates 'relevant medical history', please verify if the following Medical History conditions should be deleted or maintained:  1-Hypospadias Penis Correction 2-Lightheadedness/Vertigo 3-Appendectomy	1- <input checked="" type="checkbox"/> Delete [ ] Maintain 2- <input checked="" type="checkbox"/> Delete [ ] Maintain 3- <input checked="" type="checkbox"/> Delete [ ] Maintain
Pregnancy Test WEEK 0 (BASELINE) Disc ID: 1346044713 Type: MANUAL	5 18APR07 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"/> 18-04-2007 [ ] 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.

\_\_\_\_\_  
Authorized Personnel Signature

11 MAR 2008  
\_\_\_\_\_  
Date



## Data Clarification Form

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

Patient#: 2008  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Previous and Concomitant Medications PRECON_MEDS Disc ID: 1346096113 Type: MANUAL	26 18APR07 Closed: N	Based on dosage availability, please verify the Dose/Dose Unit to be presented for conmed Fluoxetine.	<input checked="" type="checkbox"/> Tablet Form 20 mg <input type="checkbox"/> Liquid Form 20 mg/5 ml <input type="checkbox"/> Other: _____
Usual Brand Cigarette Butt Measurement WEEK 0 (BASELINE) Disc ID: 1346082513 Type: MANUAL	5.1 19APR07 Closed: N	Please verify the dates to be presented for the Cigarette Butt Measurement data.	<input type="checkbox"/> 24 hours prior to check-in=17-04-2007 24 hours in house=18-04-2007 <input checked="" type="checkbox"/> 24 hours prior to check-in=18-04-2007 24 hours in house=19-04-2007

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

Authorized Personnel Signature

11 MAR 2008  
Date

## Data Clarification Form

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

Patient#: 2008  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
HDYF?/Oral Health Questions Inquiry WEEK 24 (EOS) Disc ID: 1346090513 Type: MANUAL	23 25APR07 Closed: N	1-Please confirm that, with the exception of the HDYF?/Oral Health Questions Inquiry & Unused Study Product Returned, all W24 should be marked BLANK? Y. 2-Verify date for HDYF?/Oral Health Questions Inquiry. 3-Verify/Provide the following Unused Study Product Returned data.	1-[ ] W24 modules BLANK? Y as noted X Other: <u>all but product returned</u> BLANK=Y 2-[ ] 25-04-2007 X Other: <u>ND</u> 3-[ ] Actual time=UNK (all) Packs returned=0 (all) X Actual time= <u>UNK</u> (all) Packs Original= <u>53</u> Packs Frost= <u>55</u> Packs Spice= <u>56</u>

On request for packs - these are pouches Dm2 031307

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Authorized Personnel Signature

Date

## Data Clarification Form

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

Patient#: 2008  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Laboratory Evaluation SCREENING Disc ID: 1346031913 Type: MANUAL	2 21MAR07 Closed: N	Please confirm the following updates to the CS? analytes fields to correctly present the clinically significant analytes.  NOTE: Lab document presenting HgBA1C CS result is not provided. Please forward with this dcf.	<input type="checkbox"/> Req # 0021426 (all) Lab Name : CCLS (all) Test Name: AST H/L: H Lab ID: C07 Test Name: GGT H/L: H Lab ID: C10 Test Name: GLucose H/L: H Lab ID: C01 Test Name: HgB A1C <input checked="" type="checkbox"/> H/L: <u>H</u> Lab ID: O-HGBA <input type="checkbox"/> As above, except: _____

①

Dm2  
031308

① entered [✓] based on H/L: — response provided Dm2 031308

② entered reg# N 528125 for HgB A1C based on attached lab reg Dm2 040208

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

Authorized Personnel Signature

11 MAR 2008

Date

**Covance CLS**

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

**LABORATORY REPORT**

\*\*\*\* REPRINTED: 18-APR-2007 \*\*\*\*

ACCESSION NO. N528129

Page 1 of 1

## INVESTIGATOR: (B18097)

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

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: 08:13 DATE: 04-Apr-2007

DATE RECEIVED IN LABORATORY: 05-Apr-2007

DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMOGLOBIN A1C

Hgb A1c

7.3

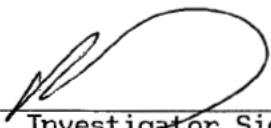
Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

QC'D

ASU MAY 2007  
Investigator Signature:  
Date:

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

B18097

(INV)

# CRF Report for Study E6270229



Patient: 2008  
CRF: Header\_Page  
Visit: SCREENING  
Entered By: Sharon Ladenes  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 21-03-2007  
Entry Time: 23-05-2007 14:27:56  
Modification Time: 12-07-2007 18:55:09  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 1  
Document #: R142728113  
CRF Status: Entry Complete

Approver:  
Verifier:

Section: Header_Info	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Section Date: 21-03-2007	
Entered By: Sharon Ladenes	Entry Time: 23-05-2007 14:27:56	
	Last Modification Time: 12-07-2007 18:55:09	
	Page number: 1	

RDC CASE REPORT FORM		SMOKER
Sponsor Name	Investigator	Site
RJ REYNOLDS TOBACCO COMPANY	PATRICIA A. CHANDLER, MD	DALLAS 002
SWITCHING FROM USUAL BRAND CIGARETTES TO A TOBACCO-HEATING CIGARETTE OR SNUS		
-A MULTI-CENTER EVALUATION OF HEALTH-RELATED QUALITY OF LIFE ASSESSMENTS AND BIOMARKERS		
OF EXPOSURE AND HARM		

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

# CRF Report for Study E6270229

Patient: 2008  
 CRF: Screening  
 Visit: SCREENING  
 Entered By: Sharon Ladenes  
 Discrepancies: Closed  
 Approval Status: Not Approved  
 Verification: Not Verified  
 Comment:

Site: CD\_001  
 Blank? N  
 Visit Date: 21-03-2007  
 Entry Time: 23-05-2007 14:28:20  
 Modification Time: 11-01-2008 16:34:25  
 Approval Time:  
 Verification Time:

Investigator: RR\_001  
 CRF Page #: 2  
 Document #: R142728213  
 CRF Status: Entry Complete  
 Approver:  
 Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:28:20	
		Last Modification Time: 17-09-2007 17:37:26	
		Page number: 2	

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

Section: Inc_Criteria	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:28:20	
		Last Modification Time: 23-05-2007 14:36:31	
		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: 2008

CRF: Screening

Visit: SCREENING

Site: CD\_001

Blank? N

Visit Date: 21-03-2007

Investigator: RR\_001

CRF Page #: 2

Document #: R142728213

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: 21-03-2007	
Entered By: Sharon Ladenes			Entry Time: 23-05-2007 14:28:20	
			Last Modification Time: 15-08-2007 17:34:14	
			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: 2008  
CRF: Screening  
Visit: SCREENING

Site: CD\_001  
Blank? N  
Visit Date: 21-03-2007

Investigator: RR\_001  
CRF Page #: 2  
Document #: R142728213

Section: Informed Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:28:20	
		Last Modification Time: 23-05-2007 14:36:31	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form		21-03-2007	

Section: Elig	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:28:20	
		Last Modification Time: 23-05-2007 14:36:31	
		Page number: 4	
Subject Eligibility			
Did the subject meet all of the inclusion criteria?		YES	
Did the subject have any of the exclusion criteria?		NO	
Criteria	Criteria		
Type	Number	Deviation	Date Exemption Granted

Section: Patient_Rep_Outc	6 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:28:20	
		Last Modification Time: 23-05-2007 14:36:31	
		Page number: 4	
Patient Reported Outcome (PRO) Questionnaires			
Did the subject complete the Smoker Screening Questionnaire prior to any study procedures being performed?			Yes / No YES

Section: Demog	7 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:28:20	
		Last Modification Time: 23-05-2007 14:36:31	
		Page number: 5	
Demographics		Subject Initials	
Date of Birth	Gender	Height	Height Unit
(b) (6)	M	188.7	CM
		xxx.x	
		Weight	Weight Unit
		115.7	KG
		xxx.x	
Ethnicity			



# CRF Report for Study E6270229



Patient: 2008  
CRF: Screening  
Visit: SCREENING

Site: CD\_001  
Blank? N  
Visit Date: 21-03-2007

Investigator: RR\_001  
CRF Page #: 2  
Document #: R142728213

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

Section: Vital		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING				Section Date: 21-03-2007			
Entered By: Sharon Ladenes				Entry Time: 23-05-2007 14:28:20			
				Last Modification Time: 23-05-2007 14:36:31			
				Page number: 5			
VITAL SIGNS							
	Blood Pressure				Oral		
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit	
1238	134	089	098	16	37.3	C	
					xxx.x		
Comments							

Section: Hdvf_Oral_Health		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING				Section Date: 21-03-2007			
Entered By: Sharon Ladenes				Entry Time: 23-05-2007 14:28:20			
				Last Modification Time: 23-05-2007 14:36:31			
				Page number: 5			
HDYF? / ORAL HEALTH QUESTIONS INQUIRY							
			Oral Health				
			Questions				
Actual Time	HDYF Performed?		Performed?		Comments		
NR	YES		YES				

Section: Lab_Eval		10 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING				Section Date: 21-03-2007			
Entered By: Sharon Ladenes				Entry Time: 23-05-2007 14:28:20			
				Last Modification Time: 11-01-2008 15:52:58			
				Page number: 6			
Laboratory Evaluations							
Were the scheduled laboratory samples obtained?				YES	No, specify		
Requisition Number 1		O021426					
Requisition Number 2 (if applicable)							
Were there any clinically significant labs?				YES	(Yes, specify below)		
Requisition Number	Test Name	H/L	Lab ID	Lab Name			

# CRF Report for Study E6270229



Patient: 2008

CRF: Screening

Visit: SCREENING

Site: CD\_001

Blank? N

Visit Date: 21-03-2007

Investigator: RR\_001

CRF Page #: 2

Document #: R142728213

Section: Lab_Eval		10 of 10
O021426	CHEMISTRY PANEL AND HBAIC	H
O021426	GLUCOSE	H

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

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

# CRF Report for Study E6270229

Patient: 2008  
CRF: Screening2  
Visit: SCREENING  
Entered By: Sharon Ladenes  
Discrepancies: Closed  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 21-03-2007  
Entry Time: 23-05-2007 14:36:32  
Modification Time: 08-01-2008 22:52:02  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 3  
Document #: R142728913  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:36:32	
		Last Modification Time: 23-05-2007 14:51:23	
		Page number: 6	
Urine Pregnancy Test			
Result			
N/A,			
MALE			
OR			
FEMA			
LE			

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:36:32	
		Last Modification Time: 23-05-2007 14:51:23	
		Page number: 6	
Urine Drug Screen			
Drug Screen Result			
NEG			

Section: Alcohol_Screen	3 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 21-03-2007	
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:36:32	
		Last Modification Time: 23-05-2007 14:51:23	
		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: 21-03-2007	

# CRF Report for Study E6270229

Patient: 2008  
CRF: Screening2  
Visit: SCREENING

Site: CD\_001  
Blank? N  
Visit Date: 21-03-2007

Investigator: RR\_001  
CRF Page #: 3  
Document #: R142728913

Section: Med\_Hx 4 of 10

Entered By: Sharon Ladenes

Entry Time: 23-05-2007 14:36:32  
Last Modification Time: 08-01-2008 22:52:02  
Page number: 7

## Medical History

Does the subject have any relevant medical history? YES  
If so, list the specific diagnosis and/or procedure.

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT	SLIGHT HEARING LOSS BOTH EARS	00-00-1970	ONGOING
BREASTS			
RESP			
CARDIO	HIGH BLOOD PRESSURE	00-00-2001	00-00-2006
LYMPH/HEMA			
GASTRO	HIATAL HERNIA	00-00-1997	ONGOING
GENITO			
MUSCULO	OSTEOARTHRITIS	00-00-1989	ONGOING
ENDOCRINE	BORDERLINE DIABETES TYPE II	00-00-2006	ONGOING
NEURO	DEPRESSION	00-00-1997	ONGOING
IMMUNO			
PSYCH			
ALLERGIC	SEASONAL ALLERGIES	00-00-1975	ONGOING
CARDIO	TACHYCARDIA	00-00-1987	ONGOING
MUSCULO	RECURRENT BACK PAIN (AUTO ACCIDENT)	00-00-1986	ONGOING
MUSCULO	RECURRENT JOINT PAIN RELATED TO OSTEOARTHRITIS	00-00-1989	ONGOING
GENITO	HYPOSPADIAS PENIS CORRECTION	00-00-1999	00-00-1999
NEURO	LIGHTEADEDNESS/VERTIGO	00-00-1965	00-00-1970
GASTRO	APPENDECTOMY	00-00-1971	00-00-1971
GASTRO	HEARTBURN	00-00-1997	ONGOING
GASTRO	GASTRO ESOPHAGEAL REFLUX DISEASE	00-00-1997	ONGOING

Section: ECG 5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 21-03-2007

Entered By: Sharon Ladenes

Entry Time: 23-05-2007 14:36:32

Last Modification Time: 23-05-2007 14:51:23

Page number: 8

## 12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time 1244 Ventricular Heart Rate 096

Cardiac Cycle Measurements

# CRF Report for Study E6270229

Patient: 2008  
CRF: Screening2  
Visit: SCREENING

Site: CD\_001  
Blank? N  
Visit Date: 21-03-2007

Investigator: RR\_001  
CRF Page #: 3  
Document #: R142728913

Section: ECG		5 of 10	
PR Interval	QRS Duration	QT Interval	QTc Interval
148	088	352	445
ECG INTERPRETATION:			
ANCS			
Comments (related to abnormal, CS findings only):			

Section: Usual_Brand_Cig		6 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 21-03-2007		Entry Time: 23-05-2007 14:36:32			
Entered By: Sharon Ladenes		Last Modification Time: 08-10-2007 15:04:46		Page number: 9			
USUAL BRAND CIGARETTE PACK DATA							
Usual Brand	Type	Length					
MARLBORO MEDIUMS	NON-MENTHOL	REGULAR <80MM					
Style	Pack	How long have these been the subject's usual brand?					
MILD/MEDIUMS	SOFT	00 months					
		10 years					

Section: Ftc_Tar_Level		7 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 21-03-2007		Entry Time: 23-05-2007 14:36:32			
Entered By: Sharon Ladenes		Last Modification Time: 08-10-2007 15:05:12		Page number: 9			
FTC TAR LEVEL OF USUAL BRAND							
FTC Tar Level (mg)							
11.4							

Section: Expired_Carbon_M		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 21-03-2007		Entry Time: 23-05-2007 14:36:32			
Entered By: Sharon Ladenes		Last Modification Time: 23-05-2007 14:51:23		Page number: 10			
EXPIRED CARBON MONOXIDE							
Actual Time	ECO Level (ppm)	%COHb	Comments				
1422	10	02.2					

Section: Best_Baseline_Sp		9 of 10		N		Entry Complete	
---------------------------	--	---------	--	---	--	----------------	--

# CRF Report for Study E6270229



Patient: 2008

CRF: Screening2

Visit: SCREENING

Site: CD\_001

Blank? N

Visit Date: 21-03-2007

Investigator: RR\_001

CRF Page #: 3

Document #: R142728913

Section: Best_Baseline_Sp	9 of 10	Blank?	Section Status:			
Visit: SCREENING		Section Date: 21-03-2007				
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:36:32				
		Last Modification Time: 08-10-2007 17:17:07				
		Page number: 10				
BEST BASELINE SPIROMETRY TEST RESULT						
Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV 1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
1251	STANDING	4.10	88	5.00	84	

Section: Irvs_Training	10 of 10	Blank? N	Section Status: Entry Complete			
Visit: SCREENING		Section Date: 21-03-2007				
Entered By: Sharon Ladenes		Entry Time: 23-05-2007 14:36:32				
		Last Modification Time: 23-05-2007 14:52:04				
		Page number: 10				
IVRS TRAINING						
Did Subject receive training on the Daily Call-In Diary (IVRS)?						
YES						

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

# CRF Report for Study E6270229

Patient: 2008  
CRF: Week-2  
Visit: WEEK -2  
Entered By: Sharon Ladenes  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 21-03-2007  
Entry Time: 23-05-2007 14:52:13  
Modification Time: 23-05-2007 14:52:33  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 4  
Document #: R142731013  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Usual_Brand_Coll	Blank? N	Section Status: Entry Complete
Visit: WEEK -2	Section Date: 21-03-2007	
Entered By: Sharon Ladenes	Entry Time: 23-05-2007 14:52:13	
	Last Modification Time: 23-05-2007 14:52:33	
	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: 2008  
CRF: Week 0 Baseline  
Visit: WEEK 0 (BASELINE)  
Entered By: Sharon Ladenes  
Discrepancies: Closed  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 18-04-2007  
Entry Time: 21-05-2007 18:59:36  
Modification Time: 11-01-2008 10:00:31  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 5  
Document #: R142502013  
CRF Status: Entry Complete

Approver:  
Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 18:59:36	
		Last Modification Time: 21-05-2007 19:01:44	
		Page number: 12A	

Date	PRO QUESTIONNAIRES	YES / NO
18-04-2007	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 18:59:36	
		Last Modification Time: 21-05-2007 19:01:44	
		Page number: 12A	

Date	Drug Screen	Drug Screen Result
18-04-2007		NEG

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 18:59:36	
		Last Modification Time: 21-05-2007 19:01:44	
		Page number: 12A	

Date	Alcohol Screen	Breathalyzer Result
18-04-2007		NEG

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 18:59:36	
		Last Modification Time: 15-08-2007 17:30:35	
		Page number: 12A	



# CRF Report for Study E6270229

Patient: 2008  
CRF: Week 0 Baseline  
Visit: WEEK 0 (BASELINE)

Site: CD\_001  
Blank? N  
Visit Date: 18-04-2007

Investigator: RR\_001  
CRF Page #: 5  
Document #: R142502013

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

Section: Urine_Coll		5 of 11	Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007		Entry Time: 21-05-2007 18:59:36		
Entered By: Sharon Ladenes		Last Modification Time: 04-12-2007 15:38:52		Page number: 12A		
24-Hour Urine Collection						
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	18-04-2007	1523	NA	NA	NA	
0 HOUR TO 24 HOURS	18-04-2007	1523	19-04-2007	1401	2350	

Section: Hdyf_Oral_Health		6 of 11	Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007		Entry Time: 21-05-2007 18:59:36		
Entered By: Sharon Ladenes		Last Modification Time: 04-12-2007 15:26:12		Page number: 13.1		
HDYF? INQUIRY						
Date	Actual Time	HDYF Performed?		Comments		
19-04-2007	0517	YES				

Section: Vital		7 of 11	Blank? N		Section Status: Entry Complete		
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007		Entry Time: 21-05-2007 18:59:36			
Entered By: Sharon Ladenes		Last Modification Time: 21-05-2007 19:03:57		Page number: 13.1			
VITAL SIGNS							
Date	Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit
18-04-2007	1336	Systolic 136	Diastolic 090	103	18	ND	ND

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CD\_001

Blank? N

Visit Date: 18-04-2007

Investigator: RR\_001

CRF Page #: 5

Document #: R142502013

Section: Vital	7 of 11	
Comments	NCS PER P.II.	xxx.x

Section: Oral_Health_Exam	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 18:59:36	
		Last Modification Time: 10-01-2008 16:43:52	
		Page number: 13.1	

ORAL HEALTH EXAMINATION			
Date	Procedure	Relevant Findings?*	Findings
18-04-2007	ORAL HEALTH QUESTIONS PERFORMED	ND	
	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: 18-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 18:59:36	
		Last Modification Time: 21-05-2007 19:04:28	
		Page number: 14.1	

PHYSICAL EXAMINATION				
Date	Code Number	Code	Relevant Findings?	Findings
18-04-2007	01	GENERAL	NO	
	02	SKIN	NO	
	03	HEENT	NO	
	04	MOUTH	NO	
	05	NECK	NO	
	06	THORAX/LUNG	NO	
	07	CARDIO	NO	
	08	ABDOMEN	NO	
	09	MUSCULO	NO	
	10	NEURO	NO	
	11	LYMPH	NO	
	12	OTHER	NE	

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

Patient: 2008

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CD\_001

Blank? N

Visit Date: 18-04-2007

Investigator: RR\_001

CRF Page #: 5

Document #: R142502013

Section: Weight_Height		10 of 11		
Visit: WEEK 0 (BASELINE)		Section Date: 18-04-2007		
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 18:59:36		
		Last Modification Time: 05-10-2007 12:39:35		
		Page number: 14.1		

WEIGHT & HEIGHT				
Date	Weight	Unit	Height	Unit
18-04-2007	115.4	KG	ND	CM
	xxx.x		xxx.x	

Section: Lab_Eval		11 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)				Section Date: 18-04-2007			
Entered By: Sharon Ladenes				Entry Time: 21-05-2007 18:59:36			
				Last Modification Time: 10-01-2008 16:47:36			
				Page number: 15.1			

Laboratory Evaluations				
Date				
19-04-2007				
Were the scheduled laboratory samples obtained?				
	Requisition Number 1	O580895	YES	No, specify
	Requisition Number 2 (if applicable)	N528046		
Were there any clinically significant labs?				
	Requisition Number	Test Name	H/L	(Yes, specify below)
	O580895	CHEMISTRY PANEL (GLUCOSE)	H	Lab ID Lab Name

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

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

# CRF Report for Study E6270229

Patient: 2008  
 CRF: Week 0 2baseline  
 Visit: WEEK 0 (BASELINE)  
 Entered By: Sharon Ladenes  
 Discrepancies: Closed  
 Approval Status: Not Approved  
 Verification: Not Verified  
 Comment:

Site: CD\_001  
 Blank? N  
 Visit Date: 19-04-2007  
 Entry Time: 21-05-2007 19:05:37  
 Modification Time: 12-12-2007 16:11:19  
 Approval Time:  
 Verification Time:

Investigator: RR\_001  
 CRF Page #: 5.1  
 Document #: R142502113  
 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: 19-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37	
		Last Modification Time: 21-05-2007 19:15:39	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
19-04-2007	0519		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37	
		Last Modification Time: 21-05-2007 19:16:01	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
19-04-2007	1425	19	03.6

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37	
		Last Modification Time: 21-05-2007 19:16:16	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
19-04-2007	1434		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37	
		Last Modification Time: 12-12-2007 16:11:19	
		Page number: 16.1	

# CRF Report for Study E6270229



Patient: 2008

Site: CD\_001

Investigator: RR\_001

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 19-04-2007

Document #: R142502113

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time							
of FEV1/FVC		Testing				FVC	
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments
19-04-2007	1453	STANDI	3.98	86	4.91	84	
		NG					

Section: Proventil_Admin	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37	
		Last Modification Time: 21-05-2007 19:16:42	
		Page number: 16.1	
PROVENTIL ADMINISTRATION			
	Actual Time of Proventil Administration	Amount Administered	Comments
Date			
19-04-2007	1549	2 METERED PUFFS	

Section: Post_Bronch_Spir	6 of 11	Blank? N	Section Status: Entry Complete				
Visit: WEEK 0 (BASELINE		Section Date: 19-04-2007					
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37					
		Last Modification Time: 06-12-2007 15:49:05					
		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						
19-04-2007	1607	STANDING	4.13	89	4.91	83	

Section: Unused_Usual_Bra	7 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37	
		Last Modification Time: 21-05-2007 19:06:51	
		Page number: 17.1	
Unused Usual Brand Cigarette Pack Collection			
			Yes / No
Date	Does Site have 5 unopened packs of subject's usual		
18-04-2007	brand cigarette to ship to CCLS?		YES

# CRF Report for Study E6270229



Patient: 2008

Site: CD\_001

Investigator: RR\_001

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 19-04-2007

Document #: R142502113

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007		Entry Time: 21-05-2007 19:05:37			
Entered By: Sharon Ladenes		Last Modification Time: 13-09-2007 18:23:49		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	17-04- 2007	1300	18-04-2007	1300	22	NO		
24 HOURS IN-HOUSE	18-04- 2007	1400	19-04-2007	1400	26	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007		Entry Time: 21-05-2007 19:05:37			
Entered By: Sharon Ladenes		Last Modification Time: 09-08-2007 12:04:47		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT																																						
Date	Scheduled Collection Period																																					
17-04-2007	24 HOURS PRIOR TO CHECK-IN																																					
		<table border="1"> <thead> <tr> <th>Cigarette Butt Number</th> <th>Cigarette Butt Measurement (mm)</th> </tr> </thead> <tbody> <tr><td>1</td><td>35</td></tr> <tr><td>2</td><td>33</td></tr> <tr><td>3</td><td>31</td></tr> <tr><td>4</td><td>30</td></tr> <tr><td>5</td><td>34</td></tr> <tr><td>6</td><td>31</td></tr> <tr><td>7</td><td>35</td></tr> <tr><td>8</td><td>35</td></tr> <tr><td>9</td><td>34</td></tr> <tr><td>10</td><td>34</td></tr> <tr><td>11</td><td>35</td></tr> <tr><td>12</td><td>40</td></tr> <tr><td>13</td><td>40</td></tr> <tr><td>14</td><td>33</td></tr> <tr><td>15</td><td>32</td></tr> <tr><td>16</td><td>38</td></tr> <tr><td>17</td><td>36</td></tr> </tbody> </table>	Cigarette Butt Number	Cigarette Butt Measurement (mm)	1	35	2	33	3	31	4	30	5	34	6	31	7	35	8	35	9	34	10	34	11	35	12	40	13	40	14	33	15	32	16	38	17	36
Cigarette Butt Number	Cigarette Butt Measurement (mm)																																					
1	35																																					
2	33																																					
3	31																																					
4	30																																					
5	34																																					
6	31																																					
7	35																																					
8	35																																					
9	34																																					
10	34																																					
11	35																																					
12	40																																					
13	40																																					
14	33																																					
15	32																																					
16	38																																					
17	36																																					

# CRF Report for Study E6270229



Patient: 2008  
CRF: Week 0 2baseline  
Visit: WEEK 0 (BASELINE)

Site: CD\_001  
Blank? N  
Visit Date: 19-04-2007

Investigator: RR\_001  
CRF Page #: 5.1  
Document #: R142502113

Section: Used_Butt_Measur	9 of 11
	18 35
	19 31
	20 35
	19 31
	20 35
	21 31
	22 51

Section: Used_Butt_Measur	10 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 19-04-2007	
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:05:37	
		Last Modification Time: 13-09-2007 18:25:40	
		Page number: 19.1	
USUAL BRAND CIGARETTE BUTT MEASUREMENT			
Date	Scheduled Collection		
19-04-2007	24 HOURS IN-HOUSE		
	Cigarette Butt Number		Cigarette Butt Measurement (mm)
	1		35
	2		37
	3		36
	4		37
	5		37
	6		37
	7		35
	8		37
	9		35
	10		32
	11		33
	12		33
	13		34
	14		35
	15		35
	16		34
	17		35
	18		35
	19		33
	20		32
	21		33
	22		35

# CRF Report for Study E6270229



Patient: 2008

Site: CD\_001

Investigator: RR\_001

CRF: Week 0 2baseline

Blank? N

CRF Page #: 5.1

Visit: WEEK 0 (BASELINE)

Visit Date: 19-04-2007

Document #: R142502113

Section: Used_Butt_Measur		10 of 11	
	23		36
	24		35
	25		34
	26		35

Section: Randomization		11 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)				Section Date: 19-04-2007			
Entered By: Sharon Ladenes				Entry Time: 21-05-2007 19:05:37			
				Last Modification Time: 21-05-2007 19:06:51			
				Page number: 20.1			
Date		RANDOMIZATION		Actual Time		Randomization Sequence	
19-04-2007				1700		GROUP B	

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



# CRF Report for Study E6270229

Patient: 2008  
CRF: Week 0 3baseline  
Visit: WEEK 0 (BASELINE)  
Entered By: Sharon Ladenes  
Discrepancies: Closed  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 19-04-2007  
Entry Time: 21-05-2007 19:16:57  
Modification Time: 12-12-2007 15:49:27  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 5.2  
Document #: R142502713  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Study_Prod_Dispe		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE		Section Date: 19-04-2007			
Entered By: Sharon Ladenes		Entry Time: 21-05-2007 19:16:57			
		Last Modification Time: 12-12-2007 15:49:27			
		Page number: 23.1			
STUDY PRODUCT DISPENSATION					
Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed	
19-04-2007	1800	SNUS	ORIGINAL	1	
19-04-2007	1800	SNUS	FROST	1	
19-04-2007	1800	SNUS	SPICE	1	

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

# CRF Report for Study E6270229

Patient: 2008  
CRF: Intercurrent\_III  
Visit: INTERCURRENT ILL  
Entered By: Sharon Ladenes  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 18-04-2007  
Entry Time: 16-07-2007 14:07:50  
Modification Time: 17-09-2007 15:01:40  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 7  
Document #: R148768413  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Ip_Findings	Blank? N	Section Status: Entry Complete
Visit: INTERCURRENT ILL	Section Date: 18-04-2007	
Entered By: Sharon Ladenes	Entry Time: 16-07-2007 14:07:50	
	Last Modification Time: 17-09-2007 15:01:40	
	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: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 1	Blank? Y	CRF Page #: 8
Visit: WEEK 1	Visit Date: 25-04-2007	Document #: R161192113
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:22	CRF Status: Created
Discrepancies: None	Modification Time: 10-01-2008 17:16:41	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 25-04-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:22		
	Last Modification Time: 10-01-2008 17:08:39		
	Page number: 22		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
	Oral Health		
	Questions		
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 25-04-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:22		
	Last Modification Time: 10-01-2008 17:08:39		
	Page number: 22		
VITAL SIGNS			
	Blood Pressure	Oral	
Actual Time	Systolic Diastolic	Temperature	Unit
	Pulse	xxx.x	
Respiratory Rate			
Comments			

Section: Expired_Carbon_M	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 25-04-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:22		
	Last Modification Time: 10-01-2008 17:08:39		
	Page number: 22		
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 25-04-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:22		
	Last Modification Time:		

# CRF Report for Study E6270229



Patient: 2008

CRF: Week 1

Visit: WEEK 1

Site: CD\_001

Blank? Y

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 8

Document #: R161192113

Section: Unused_Study_Pro		4 of 5		Page number: 23	
Unused Study Product Returned					
		Amount Returned			
Product Returned	Flavor	Packs	Individual Cigarettes / pouches		

Section: Study_Prod_Dispe	5 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 25-04-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:22		
	Last Modification Time: 10-01-2008 17:08:39		
	Page number: 23		
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

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

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 2	Blank? Y	CRF Page #: 9
Visit: WEEK 2	Visit Date: 02-05-2007	Document #: R161192213
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:55	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 02-05-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:55		
	Last Modification Time:		
	Page number: 24		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
	Oral Health		
	Questions		
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 02-05-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:55		
	Last Modification Time:		
	Page number: 24		
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Unit			
Comments			

Section: Expired_Carbon_M	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 02-05-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:55		
	Last Modification Time:		
	Page number: 24		
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Blood_Sampl_Cohb	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 2	Section Date: 02-05-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:39:55		
	Last Modification Time:		

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 2

Visit: WEEK 2

Site: CD\_001

Blank? Y

Visit Date: 02-05-2007

Investigator: RR\_001

CRF Page #: 9

Document #: R161192213

Section: Blood\_Sampl\_Cohb 4 of 6

Page number: 24

Blood Sampling for %COHb

Actual Time

Comments

Section: Unused\_Study\_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 2

Section Date: 02-05-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:39:55

Last Modification Time:

Page number: 25

Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 2

Section Date: 02-05-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:39:55

Last Modification Time:

Page number: 25

STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229



Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 4	Blank? Y	CRF Page #: 10
Visit: WEEK 4	Visit Date: 16-05-2007	Document #: R161192313
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:07	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 16-05-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:07	
		Last Modification Time:	
		Page number: 26	
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: Hdyl_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 16-05-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:07	
		Last Modification Time:	
		Page number: 26	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 16-05-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:07	
		Last Modification Time:	
		Page number: 26	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Oral Temperature
			xxx.x
Unit			
Comments			

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

# CRF Report for Study E6270229



Patient: 2008

CRF: Week 4

Visit: WEEK 4

Site: CD\_001

Blank? Y

Visit Date: 16-05-2007

Investigator: RR\_001

CRF Page #: 10

Document #: R161192313

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:07

Last Modification Time:

Page number: 26

## EXPIRED CARBON MONOXIDE

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

Section: Unused\_Study\_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 16-05-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:07

Last Modification Time:

Page number: 27

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 4

Section Date: 16-05-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:07

Last Modification Time:

Page number: 27

## STUDY PRODUCT DISPENSATION

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



Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 6	Blank? Y	CRF Page #: 11
Visit: WEEK 6	Visit Date: 30-05-2007	Document #: R161192413
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:17	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health		1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6			Section Date: 30-05-2007	
Entered By: Sharon Ladenes			Entry Time: 10-10-2007 18:40:17	
			Last Modification Time:	
			Page number: 28	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY				
Oral Health Questions				
Actual Time	HDYF Performed?	Performed?	Comments	

Section: Expired_Carbon_M		2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6			Section Date: 30-05-2007	
Entered By: Sharon Ladenes			Entry Time: 10-10-2007 18:40:17	
			Last Modification Time:	
			Page number: 28	
EXPIRED CARBON MONOXIDE				
Actual Time	ECO Level (ppm)	%COHb	Comments	

Section: Vital		3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6			Section Date: 30-05-2007	
Entered By: Sharon Ladenes			Entry Time: 10-10-2007 18:40:17	
			Last Modification Time:	
			Page number: 28	
VITAL SIGNS				
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature xxx.x
	Systolic      Diastolic			Unit
Comments				

Section: Unused_Study_Pro		4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6			Section Date: 30-05-2007	
Entered By: Sharon Ladenes			Entry Time: 10-10-2007 18:40:17	
			Last Modification Time:	

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 6

Visit: WEEK 6

Site: CD\_001

Blank? Y

Visit Date: 30-05-2007

Investigator: RR\_001

CRF Page #: 11

Document #: R161192413

Section: Unused\_Study\_Pro 4 of 5

Page number: 29

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 6

Section Date: 30-05-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:17

Last Modification Time:

Page number: 29

## STUDY PRODUCT DISPENSATION

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



Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 8	Blank? Y	CRF Page #: 13
Visit: WEEK 8	Visit Date: 13-06-2007	Document #: R161192513
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:26	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 13-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:26	
		Last Modification Time:	
		Page number: 30	
<p><b>PRO QUESTIONNAIRES</b></p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p> <p style="text-align: right;">YES / NO</p>			

Section: Hdvf_Oral_Health	2 of 6	Blank? Y	Section Status: Created												
Visit: WEEK 8		Section Date: 13-06-2007													
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:26													
		Last Modification Time:													
		Page number: 30													
<p><b>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</b></p> <table border="0" style="width: 100%;"> <tr> <td style="width: 20%;"></td> <td style="width: 20%;">Oral Health</td> <td style="width: 20%;"></td> <td style="width: 40%;"></td> </tr> <tr> <td></td> <td>Questions</td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">Actual Time</td> <td style="text-align: center;">HDYF Performed?</td> <td style="text-align: center;">Performed?</td> <td style="text-align: center;">Comments</td> </tr> </table>					Oral Health				Questions			Actual Time	HDYF Performed?	Performed?	Comments
	Oral Health														
	Questions														
Actual Time	HDYF Performed?	Performed?	Comments												

Section: Vital	3 of 6	Blank? Y	Section Status: Created																								
Visit: WEEK 8		Section Date: 13-06-2007																									
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:26																									
		Last Modification Time:																									
		Page number: 30																									
<p><b>VITAL SIGNS</b></p> <table border="0" style="width: 100%;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;">Blood Pressure</td> <td style="width: 15%;"></td> <td style="width: 15%;">Oral</td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> </tr> <tr> <td style="text-align: center;">Actual Time</td> <td style="text-align: center;">Systolic</td> <td style="text-align: center;">Diastolic</td> <td style="text-align: center;">Pulse</td> <td style="text-align: center;">Respiratory Rate</td> <td style="text-align: center;">Temperature xxx.x</td> </tr> <tr> <td style="text-align: center;">Unit</td> <td colspan="5"></td> </tr> <tr> <td colspan="6" style="text-align: center;">Comments</td> </tr> </table>					Blood Pressure		Oral			Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature xxx.x	Unit						Comments					
	Blood Pressure		Oral																								
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature xxx.x																						
Unit																											
Comments																											

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 13-06-2007	

# CRF Report for Study E6270229



Patient: 2008

CRF: Week 8

Visit: WEEK 8

Site: CD\_001

Blank? Y

Visit Date: 13-06-2007

Investigator: RR\_001

CRF Page #: 13

Document #: R161192513

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:26

Last Modification Time:

Page number: 30

## EXPIRED CARBON MONOXIDE

Actual Time

ECO Level (ppm)

%COHb

Comments

Section: Unused\_Study\_Pro 5 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 13-06-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:26

Last Modification Time:

Page number: 31

## Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 13-06-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:26

Last Modification Time:

Page number: 31

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 10	Blank? Y	CRF Page #: 14
Visit: WEEK 10	Visit Date: 27-06-2007	Document #: R161192613
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:37	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 27-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:37	
		Last Modification Time:	
		Page number: 32	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 27-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:37	
		Last Modification Time:	
		Page number: 32	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 27-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:37	
		Last Modification Time:	
		Page number: 32	
VITAL SIGNS			
Actual Time	Blood Pressure		Oral
	Systolic	Diastolic	Temperature
		Pulse	xxx.x
		Respiratory Rate	Unit
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 27-06-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:37	
		Last Modification Time:	

# CRF Report for Study E6270229



Patient: 2008

CRF: Week 10

Visit: WEEK 10

Site: CD\_001

Blank? Y

Visit Date: 27-06-2007

Investigator: RR\_001

CRF Page #: 14

Document #: R161192613

Section: Unused\_Study\_Pro 4 of 5

Page number: 33

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 5 of 5

Blank? Y

Section Status: Created

Visit: WEEK 10

Section Date: 27-06-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:40:37

Last Modification Time:

Page number: 33

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 12	Blank? Y	CRF Page #: 15
Visit: WEEK 12	Visit Date: 11-07-2007	Document #: R161192713
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:47	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnaire	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:47	
		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: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:47	
		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: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:47	
		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: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:40:47	
		Last Modification Time:	
		Page number: 34	
Pregnancy Test			

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 12

Visit: WEEK 12

Site: CD\_001

Blank? Y

Visit Date: 11-07-2007

Investigator: RR\_001

CRF Page #: 15

Document #: R161192713

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-07-2007	Entry Time: 10-10-2007 18:40:47	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 34	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
			Comments

Section: Hdyf_Oral_Health	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-07-2007	Entry Time: 10-10-2007 18:40:47	
Entered By: Sharon Ladenes	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: 11-07-2007	Entry Time: 10-10-2007 18:40:47	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 35	
VITAL SIGNS			
		Blood Pressure	Oral
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
			Temperature
			xxx.x
Comments			Unit

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-07-2007	Entry Time: 10-10-2007 18:40:47	
Entered By: Sharon Ladenes	Last Modification Time:	Page number: 35	
ORAL HEALTH EXAMINATION			



# CRF Report for Study E6270229

Patient: 2008

CRF: Week 12

Visit: WEEK 12

Site: CD\_001

Blank? Y

Visit Date: 11-07-2007

Investigator: RR\_001

CRF Page #: 15

Document #: R161192713

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: 11-07-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:47		
Last Modification Time:			
Page number: 36			

PHYSICAL EXAMINATION				
Date	Code Number	Code	Relevant Findings?	Findings

Section: Weight_Height	10 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-07-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:47		
Last Modification Time:			
Page number: 36			

WEIGHT & HEIGHT				
Date	Weight xxx.x	Unit	Height xxx.x	Unit

Section: Lab_Eval	11 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 11-07-2007		
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:40:47		
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: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 12(2)	Blank? Y	CRF Page #: 16
Visit: WEEK 12	Visit Date: 11-07-2007	Document #: R161192813
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:41:00	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:00	
		Last Modification Time:	
		Page number: 37	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:00	
		Last Modification Time:	
		Page number: 37	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
Comments			

Section: Blood_Sampl_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:00	
		Last Modification Time:	
		Page number: 37	
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:00	
		Last Modification Time:	
		Page number: 38	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 12(2)

Visit: WEEK 12

Site: CD\_001

Blank? Y

Visit Date: 11-07-2007

Investigator: RR\_001

CRF Page #: 16

Document #: R161192813

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: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:00	
	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: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:00	
		Last Modification Time:	
		Page number: 38	
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT			
	Actual Time of FEV1/FVC	Testing Position	
Date	Test	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: 11-07-2007					
Entered By: Sharon Ladenes				Entry Time: 10-10-2007 18:41:00					
				Last Modification Time:					
				Page number: 39					
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
				Number of Study Tobacco-Heating Cigarettes Collected		Weight of Cigarettes Collected (g)		Any Product Deviation?	
Scheduled Collection Timepoint		Start Date		Start Time		Stop Date		Stop Time	
								If yes, # of other Brand	
								Comments	

Section: Used_Study_Snus		8 of 11		Blank? Y		Section Status: Created	
Visit: WEEK 12		Section Date: 11-07-2007		Entry Time: 10-10-2007 18:41:00			
Entered By: Sharon Ladenes							

# CRF Report for Study E6270229

Patient: 2008  
CRF: Week 12(2)  
Visit: WEEK 12

Site: CD\_001  
Blank? Y  
Visit Date: 11-07-2007

Investigator: RR\_001  
CRF Page #: 16  
Document #: R161192813

Section: Used\_Study\_Snus 8 of 11

Last Modification Time:

Page number: 40

## USED STUDY SNUS COLLECTION

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

Section: Used\_Study\_Burn 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 11-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:00

Last Modification Time:

Page number: 41

## USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used\_Butt\_Measur 10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 11-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:00

Last Modification Time:

Page number: 42

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

Section: Used\_Butt\_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 12

Section Date: 11-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:00

Last Modification Time:

Page number: 43

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 12(3)

Visit: WEEK 12

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD\_001

Blank? Y

Visit Date: 11-07-2007

Entry Time: 10-10-2007 18:41:07

Modification Time:

Approval Time:

Verification Time:

Investigator: RR\_001

CRF Page #: 17

Document #: R161192913

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:07	
		Last Modification Time:	
		Page number: 44	
Unused Study Product Returned			
Date	Actual Time	Product Returned	Flavor
			Amount Returned
			Packs Individual Cigarettes / pouches

Section: Study_Prod_Dispe	2 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 11-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:07	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 14	Blank? Y	CRF Page #: 18
Visit: WEEK 14	Visit Date: 25-07-2007	Document #: R161193013
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:41:15	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 25-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:15	
		Last Modification Time:	
		Page number: 45	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health	
		Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 25-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:15	
		Last Modification Time:	
		Page number: 45	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 25-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:15	
		Last Modification Time:	
		Page number: 45	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Oral
	Systolic      Diastolic	Respiratory Rate	Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 25-07-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:15	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 14

Visit: WEEK 14

Site: CD\_001

Blank? Y

Visit Date: 25-07-2007

Investigator: RR\_001

CRF Page #: 18

Document #: R161193013

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: 25-07-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:15

Last Modification Time:

Page number: 46

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 16

Visit: WEEK 16

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD\_001

Blank? Y

Visit Date: 08-08-2007

Entry Time: 10-10-2007 18:41:26

Modification Time:

Approval Time:

Verification Time:

Investigator: RR\_001

CRF Page #: 19

Document #: R161193113

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 08-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:26	
		Last Modification Time:	
		Page number: 47	
<p>PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p> <p style="text-align: right;">YES / NO</p>			

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created				
Visit: WEEK 16		Section Date: 08-08-2007					
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:26					
		Last Modification Time:					
		Page number: 47					
<p>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <p>Oral Health Questions</p> <table style="width: 100%;"> <thead> <tr> <th style="width: 15%;">Actual Time</th> <th style="width: 15%;">HDYF Performed?</th> <th style="width: 15%;">Performed?</th> <th style="width: 55%;">Comments</th> </tr> </thead> </table>				Actual Time	HDYF Performed?	Performed?	Comments
Actual Time	HDYF Performed?	Performed?	Comments				

Section: Vital	3 of 6	Blank? Y	Section Status: Created												
Visit: WEEK 16		Section Date: 08-08-2007													
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:26													
		Last Modification Time:													
		Page number: 47													
<p>VITAL SIGNS</p> <table style="width: 100%;"> <thead> <tr> <th style="width: 15%;">Actual Time</th> <th style="width: 10%;">Blood Pressure</th> <th style="width: 10%;">Pulse</th> <th style="width: 15%;">Respiratory Rate</th> <th style="width: 15%;">Oral Temperature</th> <th style="width: 35%;">Unit</th> </tr> <tr> <th></th> <th>Systolic</th> <th>Diastolic</th> <th></th> <th>xxx.x</th> <th></th> </tr> </thead> </table> <p>Comments</p>				Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit		Systolic	Diastolic		xxx.x	
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit										
	Systolic	Diastolic		xxx.x											

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 08-08-2007	



# CRF Report for Study E6270229

Patient: 2008

CRF: Week 16

Visit: WEEK 16

Site: CD\_001

Blank? Y

Visit Date: 08-08-2007

Investigator: RR\_001

CRF Page #: 19

Document #: R161193113

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:26

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: 08-08-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:26

Last Modification Time:

Page number: 48

## Unused Study Product Returned

Product Returned

Flavor

Amount Returned

Packs

Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 16

Section Date: 08-08-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:26

Last Modification Time:

Page number: 48

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 18	Blank? Y	CRF Page #: 20
Visit: WEEK 18	Visit Date: 22-08-2007	Document #: R161193213
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:41:35	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 22-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:35	
		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: 22-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:35	
		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: 22-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:35	
		Last Modification Time:	
		Page number: 49	
VITAL SIGNS			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic	Diastolic	Oral Temperature
			xxx.x
Comments			Unit

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 22-08-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:35	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 18

Visit: WEEK 18

Site: CD\_001

Blank? Y

Visit Date: 22-08-2007

Investigator: RR\_001

CRF Page #: 20

Document #: R161193213

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: 22-08-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:35

Last Modification Time:

Page number: 50

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 20	Blank? Y	CRF Page #: 21
Visit: WEEK 20	Visit Date: 05-09-2007	Document #: R161193313
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:41:59	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 05-09-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:59	
		Last Modification Time:	
		Page number: 51	
<p align="center">PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p>			YES / NO

Section: Hdyl_Oral_Health	2 of 6	Blank? Y	Section Status: Created								
Visit: WEEK 20		Section Date: 05-09-2007									
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:59									
		Last Modification Time:									
		Page number: 51									
<p align="center">HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table border="0"> <tr> <td></td> <td></td> <td align="center">Oral Health Questions</td> <td></td> </tr> <tr> <td align="center">Actual Time</td> <td align="center">HDYF Performed?</td> <td align="center">Performed?</td> <td align="center">Comments</td> </tr> </table>						Oral Health Questions		Actual Time	HDYF Performed?	Performed?	Comments
		Oral Health Questions									
Actual Time	HDYF Performed?	Performed?	Comments								

Section: Vital	3 of 6	Blank? Y	Section Status: Created																												
Visit: WEEK 20		Section Date: 05-09-2007																													
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:41:59																													
		Last Modification Time:																													
		Page number: 51																													
<p align="center">VITAL SIGNS</p> <table border="0"> <tr> <td></td> <td align="center" colspan="2">Blood Pressure</td> <td></td> <td></td> <td align="center">Oral</td> <td></td> </tr> <tr> <td align="center">Actual Time</td> <td align="center">Systolic</td> <td align="center">Diastolic</td> <td align="center">Pulse</td> <td align="center">Respiratory Rate</td> <td align="center">Temperature</td> <td align="center">Unit</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td align="center">xxx.x</td> <td></td> </tr> <tr> <td colspan="7">Comments</td> </tr> </table>					Blood Pressure				Oral		Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit						xxx.x		Comments						
	Blood Pressure				Oral																										
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit																									
					xxx.x																										
Comments																															

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 05-09-2007	

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 20

Visit: WEEK 20

Site: CD\_001

Blank? Y

Visit Date: 05-09-2007

Investigator: RR\_001

CRF Page #: 21

Document #: R161193313

Section: Expired\_Carbon\_M 4 of 6

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:41:59

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: 05-09-2007

Entry Time: 10-10-2007 18:41:59

Entered By: Sharon Ladenes

Last Modification Time:

Page number: 52

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 20

Section Date: 05-09-2007

Entry Time: 10-10-2007 18:41:59

Entered By: Sharon Ladenes

Last Modification Time:

Page number: 52

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Week 22	Blank? Y	CRF Page #: 22
Visit: WEEK 22	Visit Date: 20-08-2007	Document #: R169645713
Entered By: Sharon Ladenes	Entry Time: 12-12-2007 15:55:58	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 20-08-2007	
Entered By: Sharon Ladenes		Entry Time: 12-12-2007 15:55:58	
		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: 20-08-2007	
Entered By: Sharon Ladenes		Entry Time: 12-12-2007 15:55:58	
		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: 20-08-2007	
Entered By: Sharon Ladenes		Entry Time: 12-12-2007 15:55:58	
		Last Modification Time:	
		Page number: 53	
VITAL SIGNS			
Actual Time	Blood Pressure		Oral
	Systolic	Diastolic	Pulse
			Respiratory Rate
			Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 20-08-2007	
Entered By: Sharon Ladenes		Entry Time: 12-12-2007 15:55:58	
		Last Modification Time:	

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 22

Visit: WEEK 22

Site: CD\_001

Blank? Y

Visit Date: 20-08-2007

Investigator: RR\_001

CRF Page #: 22

Document #: R169645713

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

Visit: WEEK 22

Entered By: Sharon Ladenes

Blank? Y

Section Date: 20-08-2007

Entry Time: 12-12-2007 15:55:58

Last Modification Time:

Page number: 54

Section Status: Created

## STUDY PRODUCT DISPENSATION

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

# CRF Report for Study E6270229

Patient: 2008  
CRF: Week 24 (Eos)  
Visit: WEEK 24 (EOS)  
Entered By: Sharon Ladenes  
Discrepancies: Closed  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 25-04-2007  
Entry Time: 10-10-2007 18:42:16  
Modification Time: 11-01-2008 15:02:31  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 23  
Document #: R161193513  
CRF Status: Entry Started  
Approver:  
Verifier:

Section: Pro_Questionnaire	1 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:16	
		Last Modification Time: 10-01-2008 17:30:27	
		Page number: 55	

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

Section: Urine_Drug	2 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:16	
		Last Modification Time: 10-01-2008 17:30:27	
		Page number: 55	

Date	Drug Screen	Drug Screen Result
ND		ND

Section: Alcohol_Screen	3 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:16	
		Last Modification Time: 10-01-2008 17:30:27	
		Page number: 55	

Date	Alcohol Screen	Breathalyzer Result
ND		ND

Section: Preg_Test	4 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:16	
		Last Modification Time: 10-01-2008 17:30:27	
		Page number: 55	



# CRF Report for Study E6270229

Patient: 2008

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD\_001

Blank? N

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 23

Document #: R161193513

Section: Preg\_Test

4 of 12

Pregnancy Test

Date

Result

NR

N/A,  
MALE  
OR  
FEMA  
LE

Section: Urine\_Coll

5 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time: 10-01-2008 17:30:27

Page number: 55

24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	ND	ND	ND	ND	ND	
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: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time: 10-01-2008 17:30:27

Page number: 56

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

ND

ND

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

ND

ND

ND

ND

ECG INTERPRETATION:

ND

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: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time: 11-01-2008 15:01:28

Page number: 57

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD\_001

Blank? N

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 23

Document #: R161193513

Section: Hdyf\_Oral\_Health 7 of 12

## HDYF? / ORAL HEALTH QUESTIONS INQUIRY

Date	Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
25042007	NR	YES	YES	

Section: Vital

8 of 12

Blank? N

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time:

Page number: 57

## VITAL SIGNS

### Blood Pressure

Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
ND	ND	ND	ND	ND	ND	ND	NA

xxx.x

Comments

Section: Oral\_Health\_Exam

9 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time: 11-01-2008 15:02:07

Page number: 57

## ORAL HEALTH EXAMINATION

Date	Procedure	Relevant Findings?*	Findings
ND	ORAL HEALTH QUESTIONS PERFORMED	NO	
	EVIDENCE OF LEUKOPLAKIA	ND	
	OTHER ORAL KERATOSIS	ND	

Section: Phys\_Exam

10 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time: 10-01-2008 17:30:27

Page number: 58

## PHYSICAL EXAMINATION

Date

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD\_001

Blank? N

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 23

Document #: R161193513

Section: Phys\_Exam

10 of 12

ND

Code Number

Code

Relevant Findings?

Findings

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

ND  
ND  
ND  
ND  
ND  
ND  
ND  
ND  
ND  
ND  
ND  
ND

Section: Weight\_Height

11 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time: 10-01-2008 17:30:27

Page number: 58

## WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
ND	ND		ND	
	xxx.x		xxx.x	

Section: Lab\_Eval

12 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:42:16

Last Modification Time: 10-01-2008 17:32:06

Page number: 59

## Laboratory Evaluations

Date

ND

Were the scheduled laboratory samples obtained?

ND

No, specify

Requisition Number 1

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

ND

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CD\_001

Blank? N

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 23

Document #: R161193513

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

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

# CRF Report for Study E6270229

Patient: 2008  
CRF: Week 24-2 (Eos)  
Visit: WEEK 24 (EOS)  
Entered By: Sharon Ladenes  
Discrepancies: Closed  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 25-04-2007  
Entry Time: 10-10-2007 18:42:26  
Modification Time: 11-01-2008 10:00:31  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 24  
Document #: R161193613  
CRF Status: Entry Started  
Approver:  
Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:26	
		Last Modification Time:	
		Page number: 59	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
ND	ND		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:26	
		Last Modification Time:	
		Page number: 59	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
	ND	ND	ND
			Comments

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:26	
		Last Modification Time:	
		Page number: 59	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
ND	ND		

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:26	
		Last Modification Time:	
		Page number: 60	

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CD\_001

Blank? N

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 24

Document #: R161193613

Section: Pre_Bronch_Spir			4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT								
Actual Time								
of FEV1/FVC			Testing		FVC			
Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	Predicted (%)	Comments	
ND	ND		ND	ND	ND	ND		

Section: Proventil_Admin		5 of 11	Blank? N		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007				
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:26				
		Last Modification Time:				
		Page number: 60				
PROVENTIL ADMINISTRATION						
Actual Time of Proventil Administration						
Date		Amount Administered	Comments			
ND	ND	NA				

Section: Post_Bronch_Spir		6 of 11		Blank? N		Section Status: Created			
Visit: WEEK 24 (EOS)				Section Date: 25-04-2007					
Entered By: Sharon Ladenes				Entry Time: 10-10-2007 18:42:26					
				Last Modification Time:					
				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									
ND	Date	Test	Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)		
ND	ND	ND	ND	ND	ND	ND	ND		

Section: Used_Study_Tobac		7 of 11		Blank? N		Section Status: Created			
Visit: WEEK 24 (EOS)				Section Date: 25-04-2007					
Entered By: Sharon Ladenes				Entry Time: 10-10-2007 18:42:26					
				Last Modification Time:					
				Page number: 61					
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
Scheduled Collection				Number of Study		Weight of		Any Product	
Timepoint		Start Date		Stop		Cigarettes Collected		Deviation?	
		Start Time		Stop		(g)		If yes, # of other	
				Time				Brand	
								Comments	

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CD\_001

Blank? N

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 24

Document #: R161193613

Section: Used_Study_Tobac		7 of 11						
24 HOURS PRIOR TO CHECK-IN	ND	ND	ND	ND	ND	ND	ND	ND
24 HOURS IN-HOUSE	ND	ND	ND	ND	ND	ND	ND	ND

Section: Used_Study_Snus Visit: WEEK 24 (EOS) Entered By: Sharon Ladenes	8 of 11	Blank? N Section Date: 25-04-2007 Entry Time: 10-10-2007 18:42:26 Last Modification Time: Page number: 62	Section Status: Created
--	---------	---	-------------------------

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	ND	ND	ND	
24 HOURS IN-HOUSE	ND	ND	ND	ND	ND	ND	ND	

Section: Used_Study_Burn Visit: WEEK 24 (EOS) Entered By: Sharon Ladenes	9 of 11	Blank? N Section Date: 25-04-2007 Entry Time: 10-10-2007 18:42:26 Last Modification Time: Page number: 63	Section Status: Created
--	---------	---	-------------------------

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
24 HOURS PRIOR TO CHECK-IN	ND	ND	ND	ND	ND	ND	ND	
24 HOURS IN-HOUSE	ND	ND	ND	ND	ND	ND	ND	

Section: Used_Butt_Measur Visit: WEEK 24 (EOS) Entered By: Sharon Ladenes	10 of 11	Blank? N Section Date: 25-04-2007 Entry Time: 10-10-2007 18:42:26 Last Modification Time: 10-01-2008 17:42:06 Page number: 64	Section Status: Entry Complete
---	----------	---	--------------------------------

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT	
Scheduled Collection Date	Period

# CRF Report for Study E6270229

Patient: 2008

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CD\_001

Blank? N

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 24

Document #: R161193613

Section: Used_Butt_Measur	10 of 11
ND	24 HOURS PRIOR TO CHECK-IN
	Cigarette Butt Number
	Cigarette Butt Measurement (mm)

Section: Used_Butt_Measur	11 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 25-04-2007	
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:42:26	
		Last Modification Time: 10-01-2008 17:42:06	
		Page number: 65	

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT			
Scheduled Collection			
Date	Period		
ND	24 HOURS IN-HOUSE	Cigarette Butt Number	Cigarette Butt Measurement (mm)

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



# CRF Report for Study E6270229

Patient: 2008  
CRF: Week 24-3  
Visit: WEEK 24 (EOS)  
Entered By: Sharon Ladenes  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 25-04-2007  
Entry Time: 10-10-2007 18:42:36  
Modification Time: 10-01-2008 17:56:07  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 25  
Document #: R161193713  
CRF Status: Entry Complete

Approver:  
Verifier:

Section: Unused_Study_Pro	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)	Section Date: 25-04-2007	
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:42:36	
	Last Modification Time: 10-01-2008 17:56:07	
	Page number: 65A	

## Unused Study Product Returned

Date	Actual Time	Product Returned	Flavor	Amount Returned	
				Packs	Individual Cigarettes / pouches
25-04-2007	ND	SNUS	ORIGINAL		53
25-04-2007	UNK	SNUS	FROST		55
25-04-2007	UNK	SNUS	SPICE		56

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

# CRF Report for Study E6270229

Patient: 2008  
CRF: Precon\_Med  
Visit: PRECON\_MEDS  
Entered By: Sharon Ladenes  
Discrepancies: Closed  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 18-04-2007  
Entry Time: 09-08-2007 11:54:37  
Modification Time: 11-10-2007 10:46:15  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 26  
Document #: R152214813  
CRF Status: Entry Complete  
Approver:  
Verifier:

Section: Pre_Conmed	Blank? N	Section Status: Entry Complete
Visit: PRECON_MEDS	Section Date: 18-04-2007	
Entered By: Sharon Ladenes	Entry Time: 09-08-2007 11:54:37	
	Last Modification Time: 10-10-2007 18:51:08	
	Page number: 66	

## Previous and Concomitant Medications

Has the subject taken any medications prior to the first use of study product and/or during the study as restricted by the protocol?

YES

Seq #	Drug Name	Indication	Dose / Dose Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing
1	PRILOSEC	GASTRO ESPHAGEAL REFLUX DISEASE	20 MG	PO		QD		00-00-1997	ONGOING
2	FLUOXETINE	DEPRESSION	20 ML	PO		QD		00-00-1997	ONGOING

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

# CRF Report for Study E6270229

Patient: 2008  
CRF: AE  
Visit: AE  
Entered By: Sharon Ladenes  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? N  
Visit Date: 23-04-2007  
Entry Time: 10-10-2007 18:51:40  
Modification Time: 10-10-2007 18:52:10  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 27  
Document #: R161195013  
CRF Status: Entry Complete

Approver:  
Verifier:

Section: Ae_Med		Blank? N		Section Status: Entry Complete	
Visit: AE		Section Date: 23-04-2007			
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:51:40			
		Last Modification Time: 10-10-2007 18:52:10			
		Page number: 67			

Adverse Events											
Did the subject experience any adverse events?		NO									
Event No.	Adverse Event	Date	Onset Time	Resolved/Changed Date	Time	Serious Event?	Severity	Relationship to Product	Relationship to Procedure	Action Taken	Outcome to Date

# CRF Report for Study E6270229

Patient: 2008  
CRF: Ecg\_Unscheduled  
Visit: ECG\_UNSCHEDED  
Entered By: Sharon Ladenes  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CD\_001  
Blank? Y  
Visit Date: 25-04-2007  
Entry Time: 10-10-2007 18:42:57  
Modification Time:  
Approval Time:  
Verification Time:

Investigator: RR\_001  
CRF Page #: 28  
Document #: R161193913  
CRF Status: Created

Approver:  
Verifier:

Section: ECG	Blank? Y	Section Status: Created
Visit: ECG_UNSCHEDED	Section Date: 25-04-2007	
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:42:57	
	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: 2008

CRF: Lab\_Unscheduled

Visit: LAB\_UNSCHEDED

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD\_001

Blank? N

Visit Date: 04-04-2007

Entry Time: 10-10-2007 18:43:28

Modification Time: 10-10-2007 18:44:14

Approval Time:

Verification Time:

Investigator: RR\_001

CRF Page #: 29

Document #: R161194013

CRF Status: Entry Complete

Approver:

Verifier:

Section: Lab_Eval		Blank? N		Section Status: Entry Complete			
Visit: LAB_UNSCHEDED		Section Date: 04-04-2007					
Entered By: Sharon Ladenes		Entry Time: 10-10-2007 18:43:28					
		Last Modification Time: 10-10-2007 18:44:14					
		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
04-04-2007	N528129	NO					

# CRF Report for Study E6270229

Patient: 2008	Site: CD_001	Investigator: RR_001
CRF: Vital_Unscheduled	Blank? Y	CRF Page #: 30
Visit: VITAL_UNSCHE	Visit Date: 25-04-2007	Document #: R161194113
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:44:15	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Vital	Blank? Y	Section Status: Created
Visit: VITAL_UNSCHE	Section Date: 25-04-2007	
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:44:15	
	Last Modification Time:	
	Page number: 70	

## UNSCHEDULED VITAL SIGNS

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

# CRF Report for Study E6270229

Patient: 2008

CRF: Stdy\_Prdt\_Dis\_Unscheduled

Visit: STDY\_PRDT\_UNSCHE

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD\_001

Blank? Y

Visit Date: 25-04-2007

Entry Time: 10-10-2007 18:44:24

Modification Time: 08-01-2008 22:20:47

Approval Time:

Verification Time:

Investigator: RR\_001

CRF Page #: 31

Document #: R161194213

CRF Status: Created

Approver:

Verifier:

Section: Study_Prod_Dispe	Blank? Y	Section Status: Created
Visit: STDY_PRDT_UNSCHE	Section Date: 25-04-2007	
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:44:24	
	Last Modification Time: 08-01-2008 22:20:39	
	Page number: 71	
UNSCHEDULED STUDY PRODUCT DISPENSATION		
Date	Actual Time	Product Dispensed
		Flavor
		Amount Dispensed
		Comments

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

# CRF Report for Study E6270229

Patient: 2008

CRF: Expired\_Co2\_Unscheduled

Visit: EXPIRED\_CO2\_UNSC

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD\_001

Blank? Y

Visit Date: 25-04-2007

Entry Time: 10-10-2007 18:45:11

Modification Time:

Approval Time:

Verification Time:

Investigator: RR\_001

CRF Page #: 32

Document #: R161194313

CRF Status: Created

Approver:

Verifier:

Section: Expired\_Carbon\_M

Blank? Y

Section Status: Created

Visit: EXPIRED\_CO2\_UNSC

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:45:11

Last Modification Time:

Page number: 72

## UNSCHEDULED EXPIRED CARBON MONOXIDE

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



# CRF Report for Study E6270229

Patient: 2008

CRF: Oral\_Health\_Unscheduled

Visit: ORAL\_HEALTH\_UNSC

Site: CD\_001

Blank? Y

Visit Date: 25-04-2007

Investigator: RR\_001

CRF Page #: 33

Document #: R161194413

CRF Status: Created

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:45:20

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Oral_Health_Exam	Blank? Y	Section Status: Created
Visit: ORAL_HEALTH_UNSC	Section Date: 25-04-2007	
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:45:20	
Last Modification Time:		
Page number: 73		
UNSCHEDULED ORAL HEALTH EXAMINATION		
Date	Actual Time	Code
		Relevant Findings?
		Comment

# CRF Report for Study E6270229

Patient: 2008

CRF: Spirometry\_Unscheduled

Visit: SPIRO\_TEST\_UNSCH

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD\_001

Blank? Y

Visit Date: 25-04-2007

Entry Time: 10-10-2007 18:45:28

Modification Time:

Approval Time:

Verification Time:

Investigator: RR\_001

CRF Page #: 34

Document #: R161194513

CRF Status: Created

Approver:

Verifier:

Section: Pre\_Bronch\_Spir

Blank? Y

Section Status: Created

Visit: SPIRO\_TEST\_UNSCH

Section Date: 25-04-2007

Entered By: Sharon Ladenes

Entry Time: 10-10-2007 18:45:28

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: 2008

CRF: Study\_Completion

Visit: STUDY\_COMP

Entered By: Sharon Ladenes

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CD\_001

Blank? N

Visit Date: 23-04-2007

Entry Time: 10-10-2007 18:45:37

Modification Time: 10-01-2008 17:01:09

Approval Time:

Verification Time:

Investigator: RR\_001

CRF Page #: 35

Document #: R161194613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Comp	Blank? N	Section Status: Entry Complete
Visit: STUDY_COMP	Section Date: 23-04-2007	
Entered By: Sharon Ladenes	Entry Time: 10-10-2007 18:45:37	
	Last Modification Time: 10-01-2008 17:01:09	
	Page number: 75	

Study Completion	
Did the subject complete the study?	NO
Date the subject completed OR withdrew from the study:	25-04-2007
Reason for Withdrawal	CONSENT
Specify	
Investigator Comments	
Principal Investigator	Date 11 Jan 2008

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

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0021426

Page 2 of 3

## INVESTIGATOR: (B18097)

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

## SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 14:00 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

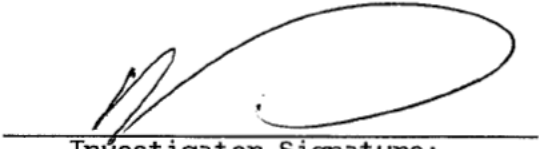
Yes

No

## HEMATOLOGY&amp; DIFFERENTIAL PANEL

HGB	16.4	12.7-18.1 g/dL
HCT	49	39-54 %
RBC	5.4	4.5-6.4 x10 <sup>6</sup> /uL
MCV	90	79-96 fL
MCH	30	26-34 pg
MCHC	34	31-38 g/dL
RDW	14.3	12.0-15.0 %
RBC Morph	Normocytic	
WBC	8.36	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	4.30	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	3.62	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.33	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.07	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.04	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	51.5	40.5-75.0 %
Lymphocyte	43.4	15.4-48.5 %
Monocytes	3.9	2.6-10.1 %
Eosinophil	0.8	0.0-6.8 %
Basophils	0.5	0.0-2.0 %
Platelets	194	140-400 x10 <sup>3</sup> /uL

QC'D

  
Investigator Signature:  
Date:

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

B18097

(INV)

**Covance CLS**

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

ACCESSION NO. 0021426

Page 3 of 3

INVESTIGATOR: (B18097)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 14:00 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

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 1.020

1.003-1.035

pH 6.0

5.0-8.0

Protein Negative

Ref Rng: Negative

Glucose Normal

Ref Rng: Normal

Ketones Negative

Ref Rng: Negative

Bilirubin Negative

Ref Rng: Negative

Urobilin Normal

Ref Rng: Normal

Blood Negative

Ref Rng: Negative

Nitrite Negative

Ref Rng: Negative

Leuk Est Negative

Ref Rng: Negative

Microscop Positive

Ref Rng: Negative

**CELLULAR ELEMENTS**

RBC 3

0-3 /HPF

**MISCELLANEOUS ELEMENTS**

Mucous Present

Ref Rng: Not present

QC'D

Investigator Signature:

Date:

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3402 Kinsman Boulevard  
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME:14:00 DATE:21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**TOTAL IRON**

Total Iron 87 45-160 ug/dL

**HEPATITIS A ANTIBODY-IGM**

HepA IgMab Negative No Ref Rng

QC'D

SE 03 Apr 2007

Investigator Signature:

02 Apr 2007  
Date:

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B18097

(INV)

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3402 Kinsman Boulevard  
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 14:00 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 23-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

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

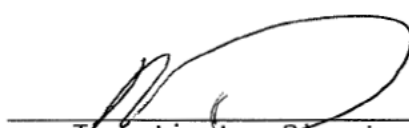
HEPATITIS B SURFACE ANTIBODY

HBSAB

Negative

No Ref Rng

QC'D

8FC3 APR 2007  
Investigator Signature:  
Date:

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(INV)

**Covance CLS**

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Page 1 of 1

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

PROTOCOL 6270-229  
INVESTIGATOR NO.: 2  
RANDOMIZATION NUMBER:  
PATIENT INITIALS: (b) (6)  
VISIT: 1

Screen  
COLLECTION TIME: 14:00 DATE: 21-Mar-2007  
DATE RECEIVED IN LABORATORY: 22-Mar-2007  
DATE REPORTED BY LABORATORY: 22-Mar-2007  
SEX: M BIRTHDATE: (b) (6) AGE: 45  
SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM

Negative

Ref Rng: Negative

QC'D

8 Feb 2007

  
Investigator Signature:

  
Date:

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B18097

(INV)



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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 14:00 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HIV 1/HIV 2 ANTIBODY SCREEN**

HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive

QC'D

SF 03 Apr 2007

  
Investigator Signature:

  
Date:

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

B18097

(INV)

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**LABORATORY REPORT**

ACCESSION NO. 0021426

Page 1 of 1

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3402 Kinsman Boulevard  
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 14:00 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

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

8F03Apr2007

  
Investigator Signature:

  
Date:

B18097

(INV)

**Covance CLS**

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

ACCESSION NO. 0021426

Page 1 of 3

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**SPONSOR REPORT TO:**

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

**Screen**

COLLECTION TIME: 14:00 DATE: 21-Mar-2007

DATE RECEIVED IN LABORATORY: 22-Mar-2007

DATE REPORTED BY LABORATORY: 22-Mar-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

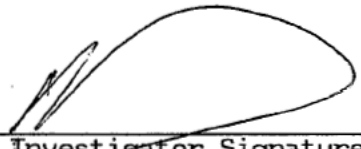
**CHEMISTRY PANEL**

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	81		31-129 U/L
ALT (SGPT)	41		6-43 U/L
AST (SGOT)	51	H	11-36 U/L
GGT	90	H	10-61 U/L
LDH	199		53-234 U/L
Urea Nitr	15		4-24 mg/dL
Creatinine	0.8		0.5-1.2 mg/dL
Glucose	134	H	70-115 mg/dL
Uric Acid	4.6		2.1-8.2 mg/dL
Calcium	10.0		8.3-10.6 mg/dL
Phosphorus	3.4		2.2-5.1 mg/dL
Total Prot	7.6		6.1-8.4 g/dL
Albumin	4.6		3.3-4.9 g/dL
Sodium	145		132-147 mEq/L
Potassium	4.6		3.4-5.4 mEq/L
Chloride	104		94-112 mEq/L

*advised  
to  
fast  
from  
alcohol*

*repeat  
chemistry panel  
fasting & also  
send HbA1c*

QC'D

Investigator Signature: 

SE 03 APR 2007

Date: 

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B18097

(INV)

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Marietta Henry, M.D., Director  
8211 SciCor Drive - Indianapolis, IN 46214-2985  
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**LABORATORY REPORT**

\*\*\*\* REPRINTED: 18-APR-2007 \*\*\*\*

ACCESSION NO. N528129

Page 1 of 1

**INVESTIGATOR: (B18097)**

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

**SPONSOR REPORT TO:**

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Retest

COLLECTION TIME: 08:13 DATE: 04-Apr-2007

DATE RECEIVED IN LABORATORY: 05-Apr-2007

DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**CHEMISTRY PANEL**

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	80		31-129 U/L
ALT (SGPT)	36		6-43 U/L
AST (SGOT)	38	H	11-36 U/L
GGT	86	H	10-61 U/L
LDH	163		53-234 U/L
Urea Nitr	18		4-24 mg/dL
Creatinine	0.9		0.5-1.2 mg/dL
Glucose	206	H	70-115 mg/dL
Uric Acid	5.7		2.1-8.2 mg/dL
Calcium	9.2		8.3-10.6 mg/dL
Phosphorus	3.8		2.2-5.1 mg/dL
Total Prot	7.0		6.1-8.4 g/dL
Albumin	4.3		3.3-4.9 g/dL
Sodium	141		132-147 mEq/L
Potassium	4.3		3.4-5.4 mEq/L
Chloride	104		94-112 mEq/L

[ ]

[ ]

[ ]

[ ]

[ ]

[ ]

QC'D

18 MAY 2007

Investigator Signature:

Date:

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B18097

(INV)

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**LABORATORY REPORT**

\*\*\*\* REPRINTED: 18-APR-2007 \*\*\*\*

ACCESSION NO. N528129

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Retest

COLLECTION TIME: 08:13 DATE: 04-Apr-2007

DATE RECEIVED IN LABORATORY: 05-Apr-2007

DATE REPORTED BY LABORATORY: 05-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HEMOGLOBIN A1C**

Hgb A1c 7.3

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

QC'D

2821 MAY 2007

Investigator Signature:



Date:

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B18097

(INV)

**LABORATORY REPORT**

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.

c/o Mark Schambura

Radiant Research Inc

1341 W Mockingbird Ln/Ste 400E

Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 24-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

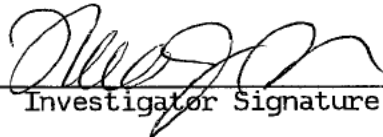
HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

QC'D

12/09/2007

  
Investigator Signature:

30 APR 2007  
Date:

B18097

(INV)



## LABORATORY REPORT

ACCESSION NO. 0580895

Page 2 of 3

## INVESTIGATOR: (B18097)

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

## SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMATOLOGY&amp; DIFFERENTIAL PANEL

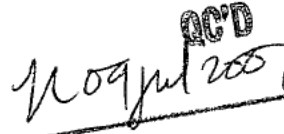
HGB	16.3		12.7-18.1 g/dL
HCT	48		39-54 %
RBC	5.4		4.5-6.4x10 <sup>6</sup> /uL
MCV	90		79-96 fL
MCH	30		26-34 pg
MCHC	34		31-38 g/dL
RDW	14.0		12.0-15.0 %
RBC Morph	Normocytic		
WBC	7.96		3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	3.52		1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	3.91		0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.35		0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.15		0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.03		0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	44.2		40.5-75.0 %
Lymphocyte	49.1	H	15.4-48.5%
Monocytes	4.4		2.6-10.1 %
Eosinophil	1.9		0.0-6.8 %
Basophils	0.4		0.0-2.0 %
Platelets	165		140-400 x10 <sup>3</sup> /uL

[ ]

[ ]



Investigator Signature:



Date:

H(High) or L(Low)=Values above or below Covance CLS reference range  
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B18097

(INV)

## LABORATORY REPORT

ACCESSION NO. 0580895

Page 3 of 3

## INVESTIGATOR: (B18097)

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

## SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

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 1.021

1.003-1.035

pH 5.0

5.0-8.0

Protein Negative

Ref Rng: Negative

Glucose +4 H

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

## CELLULAR ELEMENTS

WBC 1

0-5 /HPF

## CRYSTALS

Ca Ox Present

Ref Rng: Not present

*15 May 2007*  
*R. Dixon*  
*Diabetic*

*[Signature]*  
Investigator Signature:

*QC'D*  
*1109 Jul 2007*

*20 APR 2007*  
Date:

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B18097

(INV)



LABORATORY REPORT

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Page 1 of 1

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1341 W Mockingbird Ln/Ste 400E  
Dallas, TX 75247

PROTOCOL 6270-229  
INVESTIGATOR NO.: 2  
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: 05:19 DATE: 19-Apr-2007  
DATE RECEIVED IN LABORATORY: 20-Apr-2007  
DATE REPORTED BY LABORATORY: 20-Apr-2007  
SEX: M BIRTHDATE: (b) (6) AGE: 45  
SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes No

TOTAL IRON  
Total Iron 86 45-160 ug/dL

C-REACTIVE PROTEIN  
CRP-HS 0.408 H <=0.287 mg/dL

[ ] [X]

CARBOXYHEMOGLOBIN  
Carboxyhem 4.0 % saturation  
No Ref Rng

QCD

1104jul2007



Investigator Signature:

20 APR 2007

Date:

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

B18097

(INV)

LABORATORY REPORT

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 21-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

FIBRINOGEN

Fibrinogen

274

200-400 mg/dL

QC'D

12 April 2007

[Signature]

Investigator Signature:

30 APR 2007

Date:

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B18097

(INV)

## LABORATORY REPORT

ACCESSION NO. 0580895

Page 1 of 1

## INVESTIGATOR: (B18097)

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

## SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

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SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HOMOCYSTEINE

\*1 HCY

10.53

5.90-16.00 umol/L

QC'D

h 09/1/2007

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

Patricia Chandler  
Investigator Signature:

30 APR 2007  
Date:

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B18097

(INV)

## LABORATORY REPORT

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.

c/o Mark Schambura

Radiant Research Inc

1341 W Mockingbird Ln/Ste 400E

Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6)

AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c

7.6

Normals:

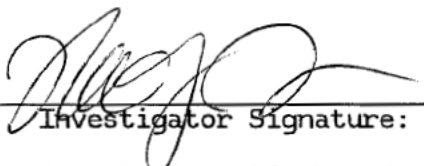
4.3-6.1%

Stable Diabetics:

4.2-11.2%

*NCS**(Essentially unchanged from baseline.)*

QC'D

*12 09 jul 2007*  
Investigator Signature:*30 APR 2007*

Date:

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B18097

(INV)

LABORATORY REPORT

\*\*\*\* REPRINTED: 22-OCT-2007 \*\*\*\*

ACCESSION NO. 0580895

Page 1 of 1

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

PROTOCOL 6270-229  
INVESTIGATOR NO.: 2  
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: 05:19 DATE: 19-Apr-2007  
DATE RECEIVED IN LABORATORY: 20-Apr-2007  
DATE REPORTED BY LABORATORY: 21-Apr-2007  
SEX: M BIRTHDATE: (b) (6) AGE: 45  
SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

FIBRINOGEN  
Fibrinogen 274 200-400 mg/dL

QC'D

*AS 20 Nov 2007*

*Wle*  
Investigator Signature:

*31 Oct 2007*  
Date:

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

B18097

(INV)

LABORATORY REPORT

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)  
 Patricia Chandler, M.D.  
 c/o Mark Schambura  
 Radiant Research Inc  
 1341 W Mockingbird Ln/Ste 400E  
 Dallas, TX 75247  
 SPONSOR REPORT TO:  
 Russell M. Dixon, MD  
 Medical Director  
 Covance CRU, Inc.  
 3402 Kinsman Boulevard  
 Madison, WI United States 53704

PROTOCOL 6270-229  
 INVESTIGATOR NO.: 2  
 RANDOMIZATION NUMBER:  
 PATIENT INITIALS: (b) (6)  
 VISIT: 2  
 Week 0  
 COLLECTION TIME: 05:19 DATE: 19-Apr-2007  
 DATE RECEIVED IN LABORATORY: 20-Apr-2007  
 DATE REPORTED BY LABORATORY: 20-Apr-2007  
 SEX: M BIRTHDATE: (b) (6) AGE: 45  
 SCREENING NUMBER: S2057

Is this Clinically  
 Significant/ Adverse  
 Event?  
 Yes No

OXIDIZED LDL  
 OxidizeLDL To follow

QC'D  
Kogul 2007

Patricia Chandler  
 Investigator Signature:

30 APR 2007  
 Date:

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

B18097

(INV)

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

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

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: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**LIPID PANEL**

Triglycer	255	55-327 mg/dL
Cholest	226	162-280 mg/dL
HDL Dex-S	40	30-64 mg/dL
LDL Chol	135	97-202 mg/dL

QC'D

*1209jul2007*

*[Signature]*  
Investigator Signature:

*30 APR 2007*  
Date:

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(INV)



LABORATORY REPORT

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 70

mg/dL No Ref Rng

QC'D

11/09/2007

Patricia Chandler  
Investigator Signature:

20 APR 2007  
Date:

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(INV)



LABORATORY REPORT

\*\*\*\* REPRINTED: 22-OCT-2007 \*\*\*\*

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.

c/o Mark Schambura

Radiant Research Inc

1341 W Mockingbird Ln/Ste 400E

Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME:05:19 DATE:19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 26-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1

sICAM-1

431

H

115-306 ng/mL

[ ]

[ ]

Investigator Signature:

Date:

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(INV)

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

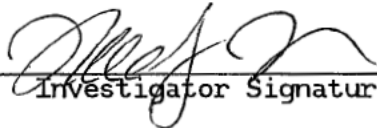
Yes

No

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

QC'D

1209jul 2007



Investigator Signature:

30 APR 2007  
Date:

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

B18097

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0580895

Page 1 of 1

INVESTIGATOR: (B18097)

Patricia Chandler, M.D.

c/o Mark Schambura

Covance-Dallas

1341 W Mockingbird Ln/Ste 400E

Dallas, TX 75247

SPONSOR REPORT TO:

Russell M. Dixon, MD

Medical Director

Covance CRU, Inc.

3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER: R2008

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 21-Jan-2008

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

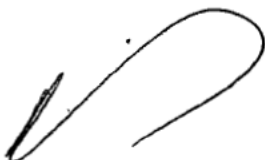
No

OXIDIZED LDL

OxidizeLDL

102

30-110 U/L



Investigator Signature:

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

Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

B18097

(INV)

QC'D  
12/20/2008

12/20/2008  
Date:

ACCESSION NO. 0580895

Page 1 of 3

INVESTIGATOR: (B18097)

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

SPONSOR REPORT TO:

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 2

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 05:19 DATE: 19-Apr-2007

DATE RECEIVED IN LABORATORY: 20-Apr-2007

DATE REPORTED BY LABORATORY: 20-Apr-2007

SEX: M BIRTHDATE: (b) (6) AGE: 45

SCREENING NUMBER: S2057

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.4		0.2-1.2 mg/dL
Alk Phos	95		31-129 U/L
ALT (SGPT)	35		6-43 U/L
AST (SGOT)	37	H	11-36 U/L
GGT	87	H	10-61 U/L
LDH	172		53-234 U/L
Urea Nitr	16		4-24 mg/dL
Creatinine	0.8		0.5-1.2 mg/dL
Glucose	201	H	70-115 mg/dL
Uric Acid	4.2		2.1-8.2 mg/dL
Calcium	9.9		8.3-10.6 mg/dL
Phosphorus	4.7		2.2-5.1 mg/dL
Total Prot	7.3		6.1-8.4 g/dL
Albumin	4.4		3.3-4.9 g/dL
Sodium	144		132-147 mEq/L
Potassium	4.0		3.4-5.4 mEq/L
Chloride	100		94-112 mEq/L

*Essentially  
unchanged  
from  
baseline  
(all)*

[ ]

[ ]

[ ]

[ ]

[ ]

[ ]

QC'D

*20 April 2007*

*[Signature]*  
Investigator Signature:

*30 APR 2007*  
Date:

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