

# CRF Report for Study E6270229

Report run by Melissa Zeis at 23-01-2008 12:38:51

Report on Selected Data

Filter: Site CDB\_001, Patient 3019

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)

## Data Clarification Form

To: Covance CRU Daytona Beach  
Investigator: Frank Farmer  
Date: 25-FEB-2008

Patient#: 3019  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Medical History SCREENING Disc ID: 1311529713 Type: MANUAL	3 30APR07 Closed: N	1-Headaches is currently noted with system EENT. Please verify if this finding is best associated with system Neurological.  2-Concomitant Therapy Ibuprofen notes an indication of Menstrual Cramps. Associated MedHx finding is Cramps. Please provide consistent verbiage.	1- <input checked="" type="checkbox"/> Neurological <input type="checkbox"/> EENT <input type="checkbox"/> Other: _____  2- <input type="checkbox"/> MedHx finding and ConMed indication=Menstrual Cramps <input type="checkbox"/> MedHx finding and ConMed indication=Cramps <input checked="" type="checkbox"/> Other: <u>Headaches and Cramps</u>
Previous and Concomitant Medications PRECON_MEDS Disc ID: 1311578413 Type: MANUAL	26 12DEC07 Closed: N	Drug Name Nuva Ring currently notes a Route and a Frequency of 'Other', however specifics are not provided.	Route <input checked="" type="checkbox"/> Vaginal <input type="checkbox"/> Other: _____ Frequency <input type="checkbox"/> Once a month <input checked="" type="checkbox"/> Other: <u>Once every 3 weeks.</u>

*Signature for #2 dated 03/19/08 no regular Dm2 03/19/08*  
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

Page ID: D11550313

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Daytona Beach  
Investigator: Frank Farmer  
Date: 25-FEB-2008

Patient#: 3019  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution	
Laboratory Evaluation WEEK 0 (BASELINE) Disc ID: 1311520713 Type: MANUAL	5 23MAY07 Closed: N	Lab Req O299955 was not signed by the PI. Please confirm this documentation was reviewed.	<input checked="" type="checkbox"/> Document was reviewed <input type="checkbox"/> Other: _____	22 10 MAR 08
Laboratory Evaluation SCREENING Disc ID: 1311523013 Type: MANUAL HEADER	30APR07 Closed: N	Clinical Significance is not provided for the Screening Hep B result of 'Positive'.	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS	22 10 MAR 08

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

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

28 Feb 2008  
\_\_\_\_\_  
Date

Page ID: D11452913

/ Covance No. 6270-229

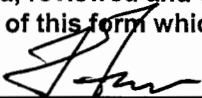
Data Clarification Form

To: Covance CRU Daytona Beach  
Investigator: Frank Farmer  
Date: 06-FEB-2008

Patient#: 3019  
Patient Initials:  
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Physical Exam WEEK 0 (BASELINE) Disc ID: 1303954913 Type: MANUAL	5 23MAY07 Closed: N	Relevant Findings for 'Other' is indicated as 'NO'. Please clarify response.	<input checked="" type="checkbox"/> Change response to 'Not Examined'. <input type="checkbox"/> Other (specify)

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 Feb 2008  
Date



# CRI Report for Study E6270229

Patient: 3019

CRF: Header\_Page

Visit: SCREENING

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 30-04-2007

Entry Time: 16-07-2007 14:09:55

Modification Time: 16-07-2007 14:17:24

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 1

Document #: R148768613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Header\_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 30-04-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 14:09:55

Last Modification Time: 16-07-2007 14:10:30

Page number: 1

RDC CASE REPORT FORM

SMOKER

Sponsor Name

Investigator

Site

RJ REYNOLDS TOBACCO COMPANY

DR FRANK FARMER

003

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

# CRI Report for Study E627022

Patient: 3019

CRF: Screening

Visit: SCREENING

Entered By: Melissa Zeis

Discrepancies: Closed

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 30-04-2007

Entry Time: 16-07-2007 14:10:31

Modification Time: 13-12-2007 09:31:34

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 2

Document #: R148768713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:10:31	
		Last Modification Time: 16-07-2007 14:12:46	
		Page number: 2	

INCLUSION CRITERIA		Yes/No
Sequence number		
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: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:10:31	
		Last Modification Time: 16-07-2007 14:12:46	
		Page number: 20	

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

# CRI Report for Study E627022

Patient: 3019

CRF: Screening

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 30-04-2007

Investigator: CDB\_001

CRF Page #: 2

Document #: R148768713

Section: Inc_Criteria		2 of 10	
11	at Screening; and for all females of child-bearing potential, the pregnancy test results must be negative at Weeks 0, 12, and 24), non-lactating, and either postmenopausal (as verified by FSH levels) for at least 1 year, surgically sterile ( e.g, tubal ligation, hysterectomy, etc.) for at least 90 days, or agree to use from the time of signing the informed consent until 30 days after Week 24 (of Study Completion) a form of contraception considered acceptable to the Investigators (such as oral, injectable, or implantable contraceptives, intrauterine devices and barrier methods).		YES
12	Able to comprehend and willing to sign an Informed Consent Form (ICF).		YES
13	Able to read and comprehend questionnaires in English.		YES

Section: Exc_Criteria		3 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING			Section Date: 30-04-2007	
Entered By: Melissa Zeis			Entry Time: 16-07-2007 14:10:31	
			Last Modification Time: 16-07-2007 14:12:46	
			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: 3019

CRF: Screening

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 30-04-2007

Investigator: CDB\_001

CRF Page #: 2

Document #: R148768713

Section: Informed_Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:10:31	
		Last Modification Time: 16-07-2007 14:17:50	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form		30-04-2007	

Section: Elig	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:10:31	
		Last Modification Time: 16-07-2007 14:12:46	
		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: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:10:31	
		Last Modification Time: 16-07-2007 14:12:46	
		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: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:10:31	
		Last Modification Time: 12-12-2007 16:25:50	
		Page number: 5	
Demographics		Subject Initials	
Date of Birth	Gender	Height	Height Unit
(b) (6)	F	171.4	CM
		xxx.x	
		Weight	Weight Unit
		91.4	KG
		xxx.x	
Ethnicity			

# CRI Report for Study E6270229

Patient: 3019  
CRF: Screening  
Visit: SCREENING

Site: CDB\_001  
Blank? N  
Visit Date: 30-04-2007

Investigator: CDB\_001  
CRF Page #: 2  
Document #: R148768713

Section: Demog	7 of 10	
Hispanic or Latino? UNK	Race WHITE	Race other

Section: Vital	8 of 10	Blank? N	Section Status: Entry Complete		
Visit: SCREENING	Entered By: Melissa Zeis	Section Date: 30-04-2007 Entry Time: 16-07-2007 14:10:31 Last Modification Time: 16-07-2007 14:12:46 Page number: 5			
VITAL SIGNS					
Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit
1143	Systolic 105	Diastolic 73	75	18	36.9 xxx.x C
Comments					

Section: Hdyf_Oral_Health	9 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Entered By: Melissa Zeis	Section Date: 30-04-2007 Entry Time: 16-07-2007 14:10:31 Last Modification Time: 16-07-2007 14:12:46 Page number: 5	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Actual Time	HDYF Performed?	Oral Health Questions Performed?	Comments
NR	YES	YES	

Section: Lab_Eval	10 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING	Entered By: Melissa Zeis	Section Date: 30-04-2007 Entry Time: 16-07-2007 14:10:31 Last Modification Time: 16-07-2007 14:12:46 Page number: 6	
Laboratory Evaluations			
Were the scheduled laboratory samples obtained?		YES	No, specify
Requisition Number 1		N746068	
Requisition Number 2 (if applicable)			
Were there any clinically significant labs?		NO	(Yes, specify below)
Requisition Number	Test Name	H/L	Lab ID Lab Name

# CRI Report for Study E6270229

Patient: 3019

CRF: Screening2

Visit: SCREENING

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 30-04-2007

Entry Time: 16-07-2007 14:12:47

Modification Time: 10-01-2008 17:33:03

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 3

Document #: R148768813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:12:47	
		Last Modification Time: 16-07-2007 14:16:09	
		Page number: 6	
Urine Pregnancy Test			
Result			
NEGA			
TIVE			

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:12:47	
		Last Modification Time: 16-07-2007 14:16:09	
		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: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:12:47	
		Last Modification Time: 16-07-2007 14:16:09	
		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: 30-04-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:12:47	
		Last Modification Time: 10-01-2008 17:33:03	
		Page number: 7	

# CRI Report for Study E627022

Patient: 3019

CRF: Screening2

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 30-04-2007

Investigator: CDB\_001

CRF Page #: 3

Document #: R148768813

Section: Med_Hx		4 of 10	
Medical History			
Does the subject have any relevant medical history?		YES	
If so, list the specific diagnosis and/or procedure.			
System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT	HEADACHES	00-00-1989	ONGOING
BREASTS			
RESP			
CARDIO			
LYMPH/HEMA			
GASTRO			
GENITO	CRAMPS	00-00-1989	ONGOING
MUSCULO			
ENDOCRINE			
NEURO			
IMMUNO			
PSYCH			
ALLERGIC			
OTHER			

Section: ECG		5 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Entered By: Melissa Zeis		Section Date: 30-04-2007		Entry Time: 16-07-2007 14:12:47	
				Last Modification Time: 16-07-2007 14:16:09		Page number: 8	
12-LEAD ELECTROCARDIOGRAM REPORT							
Actual Time		Ventricular Heart Rate					
1151		60					
Cardiac Cycle Measurements							
PR Interval		QRS Duration		QT Interval		QTc Interval	
146		96		454		454	
ECG INTERPRETATION:							
NORMAL							
Comments (related to abnormal, CS findings only):							

Section: Usual_Brand_Cig		6 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Entered By: Melissa Zeis		Section Date: 30-04-2007		Entry Time: 16-07-2007 14:12:47	
				Last Modification Time: 12-12-2007 16:26:44			

# CRF Report for Study E6270220

Patient: 3019  
CRF: Screening2  
Visit: SCREENING

Site: CDB\_001  
Blank? N  
Visit Date: 30-04-2007

Investigator: CDB\_001  
CRF Page #: 3  
Document #: R148768813

Section: Usual_Brand_Cig		6 of 10		Page number: 9	
USUAL BRAND CIGARETTE PACK DATA					
Usual Brand	Type	Length			
MALBORO	NON-MENTHOL	KING SIZE 83-85MM			
How long have these been the subject's usual brand?					
Style	Pack	4 months			
MILD/MEDIUMS	HARD	0 years			

Section: Ftc_Tar_Level		7 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 30-04-2007					
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:12:47					
		Last Modification Time: 16-07-2007 14:16:09					
		Page number: 9					
FTC TAR LEVEL OF USUAL BRAND							
FTC Tar Level (mg)							
11.3							

Section: Expired_Carbon_M		8 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 30-04-2007					
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:12:47					
		Last Modification Time: 16-07-2007 14:16:09					
		Page number: 10					
EXPIRED CARBON MONOXIDE							
Actual Time	ECO Level (ppm)	%COHb	Comments				
1131	11	2.3					

Section: Best_Baseline_Sp		9 of 10		Blank? N		Section Status: Entry Complete	
Visit: SCREENING		Section Date: 30-04-2007					
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:12:47					
		Last Modification Time: 16-07-2007 14:16:09					
		Page number: 10					
BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time	Testing Position	FEV1 L	FEV 1 Predicted (%)	FVC L	FVC Predicted (%)	Comments	
of FEV1/FVC Test							
1202	STANDING	3.56	102	4.59	109		

lrvs Training	10	10	N	Entry Complete
---------------	----	----	---	----------------



# CRF Report for Study E6270229

Patient: 3019

CRF: Screening2

Visit: SCREENING

Site: CDB\_001

Blank? N

Visit Date: 30-04-2007

Investigator: CDB\_001

CRF Page #: 3

Document #: R148768813

Section: Irvs_Training	10 of 10	Blank?	Section Date: 30-04-2007	Section Status:
Visit: SCREENING			Entry Time: 16-07-2007 14:12:47	
Entered By: Melissa Zeis			Last Modification Time: 16-07-2007 14:16:09	
		Page number: 10		
IVRS TRAINING				
Did Subject receive training on the Daily Call-In Diary (IVRS)?				
YES				

# CRF Report for Study E627022

Patient: 3019

CRF: Week-2

Visit: WEEK -2

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 11-05-2007

Entry Time: 16-07-2007 14:16:10

Modification Time: 16-07-2007 14:17:07

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 4

Document #: R148768913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Usual\_Brand\_Coll

Blank? N

Section Status: Entry Complete

Visit: WEEK -2

Section Date: 11-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 14:16:10

Last Modification Time: 16-07-2007 14:17:07

Page number: 11

## USUAL BRAND

## CIGARETTE COLLECTION TRAINING

- |  |     |
|--|-----|
| 1. Did subject receive foam block?   | YES |
| 2. Did subject receive training on usual brand collection?                           | YES |
| 3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection? | YES |

# CRI Report for Study E627022

Patient: 3019

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Entry Time: 16-07-2007 14:18:41

Modification Time: 10-01-2008 17:38:56

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 5

Document #: R148769113

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41	
		Last Modification Time: 16-07-2007 14:23:05	
		Page number: 12A	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject	YES / NO	
23-05-2007	complete Smoker Routine Questionnaire PRIOR to any		
	study procedures being performed?	YES	

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41	
		Last Modification Time: 16-07-2007 14:23:05	
		Page number: 12A	
Drug Screen			
Date	Drug Screen Result		
23-05-2007	NEG		

Section: Alcohol_Screen	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41	
		Last Modification Time: 16-07-2007 14:23:05	
		Page number: 12A	
Alcohol Screen			
Date	Breathalyzer Result		
23-05-2007	NEG		

Section: Preg_Test	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41	
		Last Modification Time: 16-07-2007 14:23:05	
		Page number: 12A	

# CRI Report for Study E627022

Patient: 3019

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB\_001

CRF Page #: 5

Document #: R148769113

Section: Preg_Test		4 of 11	
Pregnancy Test			
Date	Result		
23-05-2007	NEGA TIVE		

Section: Urine_Coll		5 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007					
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41					
		Last Modification Time: 12-12-2007 16:27:31					
		Page number: 12A					
24-Hour Urine Collection							
Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments	
SPOT URINE VOID	23-05-2007	1523	NA	NA	NA		
0 HOUR TO 24 HOURS	23-05-2007	1523	24-05-2007	1523	3100		

Section: Hdvt_Oral_Health		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007					
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41					
		Last Modification Time: 16-07-2007 14:23:05					
		Page number: 13.1					
HDYF? INQUIRY							
Date	Actual Time	HDYF Performed?		Comments			
24-05-2007	0527	YES					

Section: Vital		7 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007					
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41					
		Last Modification Time: 16-07-2007 14:23:05					
		Page number: 13.1					
VITAL SIGNS							
Blood Pressure							
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
23-05-2007	1537	121	80	77	16	37.0 xxx.x	C
Comments							

# CRI Report for Study E627022

Patient: 3019

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB\_001

CRF Page #: 5

Document #: R148769113

Section: Oral_Health_Exam	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41	
		Last Modification Time: 16-07-2007 14:23:05	
		Page number: 13.1	

## ORAL HEALTH EXAMINATION

Date  
24-05-2007

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

Section: Phys_Exam	9 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41	
		Last Modification Time: 16-07-2007 14:23:05	
		Page number: 14.1	

## PHYSICAL EXAMINATION

Date  
24-05-2007

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

Section: Weight_Height	10 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:18:41	
		Last Modification Time: 12-12-2007 16:28:21	
		Page number: 14.1	

# CRI Report for Study E627022

Patient: 3019

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB\_001

CRF Page #: 5

Document #: R148769113

Section: Weight_Height		10 of 11		
WEIGHT & HEIGHT				
Date	Weight	Unit	Height	Unit
23-05-2007	91.1	KG	ND	
	xxx.x		xxx.x	

Section: Lab_Eval		11 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007		Entry Time: 16-07-2007 14:18:41			
Entered By: Melissa Zeis		Last Modification Time: 10-01-2008 17:38:56		Page number: 15.1			
Laboratory Evaluations							
Date							
23-05-2007							
Were the scheduled laboratory samples obtained?			YES	No, specify			
Requisition Number 1			P205169				
Requisition Number 2 (if applicable)							
Were there any clinically significant labs?			NO	(Yes, specify below)			
24-05-2007							
			YES				
O299955							
NO							
Requisition Number	Test Name	H/L	Lab ID	Lab Name			

# CRI Report for Study E6270220

Patient: 3019	Site: CDB_001	Investigator: CDB_001
CRF: Week 0 2baseline	Blank? N	CRF Page #: 5.1
Visit: WEEK 0 (BASELINE)	Visit Date: 23-05-2007	Document #: R148769213
Entered By: Melissa Zeis	Entry Time: 16-07-2007 14:23:08	CRF Status: Entry Complete
Discrepancies: None	Modification Time: 12-12-2007 16:32:08	
Approval Status: Not Approved	Approval Time:	Approver:
Verification: Not Verified	Verification Time:	Verifier:
Comment:		

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete						
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007							
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08							
		Last Modification Time: 16-07-2007 14:40:14							
		Page number: 15.1							
<p>Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Actual Time</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>24-05-2007</td> <td>0629</td> <td></td> </tr> </tbody> </table>				Date	Actual Time	Comments	24-05-2007	0629	
Date	Actual Time	Comments							
24-05-2007	0629								

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete										
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007											
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08											
		Last Modification Time: 16-07-2007 14:40:14											
		Page number: 15.1											
<p>EXPIRED CARBON MONOXIDE</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Actual Time</th> <th>ECO Level (ppm)</th> <th>%COHb</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>24-05-2007</td> <td>1110</td> <td>25</td> <td>4.6</td> <td></td> </tr> </tbody> </table>				Date	Actual Time	ECO Level (ppm)	%COHb	Comments	24-05-2007	1110	25	4.6	
Date	Actual Time	ECO Level (ppm)	%COHb	Comments									
24-05-2007	1110	25	4.6										

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete						
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007							
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08							
		Last Modification Time: 16-07-2007 14:40:14							
		Page number: 15.1							
<p>Blood Sampling for %COHb</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Actual Time</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td>24-05-2007</td> <td>1113</td> <td></td> </tr> </tbody> </table>				Date	Actual Time	Comments	24-05-2007	1113	
Date	Actual Time	Comments							
24-05-2007	1113								

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08	
		Last Modification Time: 12-12-2007 16:30:16	
		Page number: 16.1	

# CRI Report for Study E627022

Patient: 3019

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB\_001

CRF Page #: 5.1

Document #: R148769213

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
24-05-2007	1324	STANDI NG	3.60	102	4.43	106	

Section: Proventil_Admin	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08	
		Last Modification Time: 16-07-2007 14:40:14	
		Page number: 16.1	
PROVENTIL ADMINISTRATION			
	Actual Time of Proventil Administration	Amount Administered	Comments
Date			
24-05-2007	1327	2 METERED PUFFS	

Section: Post_Bronch_Spir		6 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007					
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08					
		Last Modification Time: 12-12-2007 16:32:08					
		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						
24-05-2007	1342	STANDING	3.67	105	4.32	103	

Section:	Unused_Usual_Bra	7 of 11	Blank?	N	Section Status:	Entry Complete
Visit:	WEEK 0 (BASELINE)		Section Date:	23-05-2007		
Entered By:	Melissa Zeis		Entry Time:	16-07-2007 14:23:08		
			Last Modification Time:	16-07-2007 14:40:14		
			Page number:	17.1		
Unused Usual Brand Cigarette Pack Collection						
					Yes / No	
Date	Does Site have 5 unopened packs of subject's usual					
24-05-2007	brand cigarette to ship to CCLS?					YES



# CRI Report for Study E627022

Patient: 3019

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB\_001

CRF Page #: 5.1

Document #: R148769213

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)				Section Date: 23-05-2007			
Entered By: Melissa Zeis				Entry Time: 16-07-2007 14:23:08			
				Last Modification Time: 16-07-2007 14:40:14			
				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	22-05- 2007	1500	23-05-2007	1500	28	NO		
24 HOURS IN-HOUSE	23-05- 2007	1500	24-05-2007	1500	37	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)				Section Date: 23-05-2007			
Entered By: Melissa Zeis				Entry Time: 16-07-2007 14:23:08			
				Last Modification Time: 16-07-2007 14:40:14			
				Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT																																						
Date	Scheduled Collection Period																																					
23-05-2007	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>43</td></tr> <tr><td>2</td><td>43</td></tr> <tr><td>3</td><td>44</td></tr> <tr><td>4</td><td>47</td></tr> <tr><td>5</td><td>42</td></tr> <tr><td>6</td><td>37</td></tr> <tr><td>7</td><td>39</td></tr> <tr><td>8</td><td>48</td></tr> <tr><td>9</td><td>41</td></tr> <tr><td>10</td><td>43</td></tr> <tr><td>11</td><td>44</td></tr> <tr><td>12</td><td>34</td></tr> <tr><td>13</td><td>44</td></tr> <tr><td>14</td><td>46</td></tr> <tr><td>15</td><td>44</td></tr> <tr><td>16</td><td>46</td></tr> <tr><td>17</td><td>45</td></tr> </tbody> </table>	Cigarette Butt Number	Cigarette Butt Measurement (mm)	1	43	2	43	3	44	4	47	5	42	6	37	7	39	8	48	9	41	10	43	11	44	12	34	13	44	14	46	15	44	16	46	17	45
Cigarette Butt Number	Cigarette Butt Measurement (mm)																																					
1	43																																					
2	43																																					
3	44																																					
4	47																																					
5	42																																					
6	37																																					
7	39																																					
8	48																																					
9	41																																					
10	43																																					
11	44																																					
12	34																																					
13	44																																					
14	46																																					
15	44																																					
16	46																																					
17	45																																					

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB\_001

CRF Page #: 5.1

Document #: R148769213

Section: Used_Butt_Measur	9 of 11
18	47
19	45
20	45
21	45
22	48
23	33
24	46
25	47
26	46
27	47
28	52

Section: Used_Butt_Measur	10 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08	
		Last Modification Time: 16-07-2007 14:40:14	
		Page number: 19.1	

USUAL BRAND CIGARETTE BUTT MEASUREMENT	
Date	Scheduled Collection
24-05-2007	24 HOURS IN-HOUSE
Cigarette Butt Number	Cigarette Butt Measurement (mm)
1	44
2	41
3	41
4	46
5	45
6	44
7	45
8	38
9	41
10	40
11	42
12	43
13	44
14	43
15	44
16	44
17	43
18	42

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 0 2baseline

Visit: WEEK 0 (BASELINE)

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Investigator: CDB\_001

CRF Page #: 5.1

Document #: R148769213

Section: Used_Butt_Measur	10 of 11
19	43
20	45
21	41
22	47
23	46
24	48
25	49
26	48
27	48
28	47
29	46
30	42
31	41
32	48
33	45
34	46
35	42
36	45
37	41

Section: Randomization	11 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:23:08	
		Last Modification Time: 16-07-2007 14:40:14	
		Page number: 20.1	
Date	RANDOMIZATION	Actual Time	Randomization Sequence
24-05-2007		1351	GROUP B

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 0 3baseline

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 24-05-2007

Entry Time: 16-07-2007 14:40:15

Modification Time: 12-12-2007 16:33:01

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 5.2

Document #: R148770113

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study\_Prod\_Dispe

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 24-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 14:40:15

Last Modification Time: 12-12-2007 16:33:01

Page number: 23.1

## STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
24-05-2007	1530	SNUS	ORIGINAL	1
24-05-2007	1530	SNUS	FROST	1
24-05-2007	1530	SNUS	SPICE	1

# CRI Report for Study E6270229

Patient: 3019

CRF: Intercurrent\_III

Visit: INTERCURRENT ILL

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 23-05-2007

Entry Time: 16-07-2007 15:20:29

Modification Time: 16-07-2007 15:20:35

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 7

Document #: R148781213

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ip\_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 23-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 15:20:29

Last Modification Time: 16-07-2007 15:20:35

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

# CRI Report for Study E627022

Patient: 3019

CRF: Week 1

Visit: WEEK 1

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:33:58

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 8

Document #: R169646313

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:33:58	
		Last Modification Time:	
		Page number: 22	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:33:58	
		Last Modification Time:	
		Page number: 22	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic Diastolic	xxx.x	
Comments			

Section: Expired_Carbon_M	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:33:58	
		Last Modification Time:	
		Page number: 22	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:33:58	
		Last Modification Time:	

# CRI Report for Study E627022

Patient: 3019

CRF: Week 1

Visit: WEEK 1

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 8

Document #: R169646313

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

Section: Study_Prod_Dispe	5 of 5	Blank? Y	Section Status: Created
Visit: WEEK 1	Section Date: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:33:58		
Last Modification Time:			
Page number: 23			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

# CRF Report for Study E6270229

Patient: 3019	Site: CDB_001	Investigator: CDB_001
CRF: Week 2	Blank? Y	CRF Page #: 9
Visit: WEEK 2	Visit Date: 12-12-2007	Document #: R169646413
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:34:06	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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:06	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:06	
		Last Modification Time:	
		Page number: 24	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:06	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:06	
		Last Modification Time:	



# CRI Report for Study E6270229

Patient: 3019

CRF: Week 2

Visit: WEEK 2

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 9

Document #: R169646413

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: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:34:06		
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: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:34:06		
Last Modification Time:			
Page number: 25			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

# CRI Report for Study E6270229



Patient: 3019  
 CRF: Week 4  
 Visit: WEEK 4  
 Entered By: Melissa Zeis  
 Discrepancies: None  
 Approval Status: Not Approved  
 Verification: Not Verified  
 Comment:

Site: CDB\_001  
 Blank? Y  
 Visit Date: 12-12-2007  
 Entry Time: 12-12-2007 16:34:12  
 Modification Time:  
 Approval Time:  
 Verification Time:

Investigator: CDB\_001  
 CRF Page #: 10  
 Document #: R169646513  
 CRF Status: Created  
 Approver:  
 Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:12	
		Last Modification Time:	
		Page number: 26	
PRO QUESTIONNAIRES With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			
			YES / NO

Section: HDYF_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 4		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:12	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:12	
		Last Modification Time:	
		Page number: 26	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic      Diastolic	xxx.x	
	Pulse	Respiratory Rate	
Comments			

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

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 4

Visit: WEEK 4

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 10

Document #: R169646513

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:12

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:12

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:12

Last Modification Time:

Page number: 27

## STUDY PRODUCT DISPENSATION

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

# CRI Report for Study E627022

Patient: 3019

CRF: Week 6

Visit: WEEK 6

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:34:20

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 11

Document #: R169646613

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 6		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:20	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:20	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:20	
		Last Modification Time:	
		Page number: 28	
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 6		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:20	
		Last Modification Time:	

# CRI Report for Study E627022

Patient: 3019

CRF: Week 6

Visit: WEEK 6

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 11

Document #: R169646613

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:20

Last Modification Time:

Page number: 29

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRI Report for Study E627022

Patient: 3019

CRF: Week 8

Visit: WEEK 8

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:34:44

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 13

Document #: R169646813

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:44	
		Last Modification Time:	
		Page number: 30	
PRO QUESTIONNAIRES			
With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?			YES / NO

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:44	
		Last Modification Time:	
		Page number: 30	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Oral Health Questions			
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 8		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:44	
		Last Modification Time:	
		Page number: 30	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		xxx.x	
Comments			

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

# CRI Report for Study E627022

Patient: 3019

CRF: Week 8

Visit: WEEK 8

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 13

Document #: R169646813

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:44

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:44

Last Modification Time:

Page number: 31

## Unused Study Product Returned

Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study\_Prod\_Dispe 6 of 6

Blank? Y

Section Status: Created

Visit: WEEK 8

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:44

Last Modification Time:

Page number: 31

## STUDY PRODUCT DISPENSATION

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

# CRI Report for Study E627022

Patient: 3019

CRF: Week 10

Visit: WEEK 10

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:34:51

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 14

Document #: R169646913

CRF Status: Created

Approver:

Verifier:

Section: HdyL_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:51	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:51	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:51	
		Last Modification Time:	
		Page number: 32	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral	
	Systolic	Diastolic	
	Pulse	Respiratory Rate	
		Temperature	
		xxx.x	
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 10		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:51	
		Last Modification Time:	



# CRI Report for Study E627022

Patient: 3019

CRF: Week 10

Visit: WEEK 10

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 14

Document #: R169646913

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:34:51

Last Modification Time:

Page number: 33

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 12

Visit: WEEK 12

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:34:59

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 15

Document #: R169647013

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionair	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		Last Modification Time:	
		Page number: 34	

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

Section: Urine_Drug	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		Last Modification Time:	
		Page number: 34	

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

Section: Alcohol_Screen	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		Last Modification Time:	
		Page number: 34	

Date	Alcohol Screen	Breathalyzer Result
------	----------------	---------------------

Section: Preg_Test	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		Last Modification Time:	
		Page number: 34	

Pregnancy Test

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 12

Visit: WEEK 12

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 15

Document #: R169647013

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		Last Modification Time:	
		Page number: 35	
VITAL SIGNS			
		Blood Pressure	Oral
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
			Temperature
			Unit
			xxx.x
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		Last Modification Time:	
		Page number: 35	
ORAL HEALTH EXAMINATION			

# CRI Report for Study E627022

Patient: 3019

CRF: Week 12

Visit: WEEK 12

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 15

Document #: R169647013

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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		Last Modification Time:	
		Page number: 36	
WEIGHT & HEIGHT			
Date	Weight	Unit	Height
	xxx.x		xxx.x

Section: Lab_Eval	11 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:34:59	
		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

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 12(2)

Visit: WEEK 12

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:35:09

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 16

Document #: R169647113

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:09	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:09	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:09	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:09	
		Last Modification Time:	
		Page number: 38	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

# CRI Report for Study E627022

Patient: 3019

CRF: Week 12(2)

Visit: WEEK 12

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 16

Document #: R169647113

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

Section: Proventil_Admin	5 of 11	Blank? Y	Section Date: 12-12-2007	Section Status: Created
Visit: WEEK 12			Entry Time: 12-12-2007 16:35:09	
Entered By: Melissa Zeis		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 Date: 12-12-2007	Section Status: Created
Visit: WEEK 12			Entry Time: 12-12-2007 16:35:09	
Entered By: Melissa Zeis		Last Modification Time:		
		Page number: 38		

POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
	Actual Time of FEV1/FVC	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						

Section: Used Study Tobac	7 of 11	Blank? Y	Section Date: 12-12-2007	Section Status: Created
Visit: WEEK 12			Entry Time: 12-12-2007 16:35:09	
Entered By: Melissa Zeis		Last Modification Time:		
		Page number: 39		

USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION							
Scheduled Collection			Number of Study Tobacco-Heating		Weight of		
Timepoint	Start Date	Start Time	Stop Date	Stop Time	Cigarettes Collected	Cigarettes Collected (g)	Any Product Deviation?
							If yes, # of other Brand
							Comments

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Date: 12-12-2007	Section Status: Created
Visit: WEEK 12			Entry Time: 12-12-2007 16:35:09	
Entered By: Melissa Zeis				

# CRI Report for Study E627022

Patient: 3019  
CRF: Week 12(2)  
Visit: WEEK 12

Site: CDB\_001  
Blank? Y  
Visit Date: 12-12-2007

Investigator: CDB\_001  
CRF Page #: 16  
Document #: R169647113

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:09

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:09

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:09

Last Modification Time:

Page number: 43

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

# CRI Report for Study E627022

Patient: 3019  
CRF: Week 12(3)  
Visit: WEEK 12  
Entered By: Melissa Zeis  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CDB\_001  
Blank? Y  
Visit Date: 12-12-2007  
Entry Time: 12-12-2007 16:35:17  
Modification Time:  
Approval Time:  
Verification Time:

Investigator: CDB\_001  
CRF Page #: 17  
Document #: R169647213  
CRF Status: Created

Approver:  
Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:17	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:17	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed



# CRI Report for Study E627022

Patient: 3019

CRF: Week 14

Visit: WEEK 14

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:35:25

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 18

Document #: R169647313

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:25	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:25	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:25	
		Last Modification Time:	
		Page number: 45	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic      Diastolic	xxx.x	
	Pulse	Respiratory Rate	
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:25	
		Last Modification Time:	

# CRI Report for Study E627022

Patient: 3019

CRF: Week 14

Visit: WEEK 14

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 18

Document #: R169647313

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:25

Last Modification Time:

Page number: 46

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRI Report for Study E627022

Patient: 3019	Site: CDB_001	Investigator: CDB_001
CRF: Week 16	Blank? Y	CRF Page #: 19
Visit: WEEK 16	Visit Date: 12-12-2007	Document #: R169647413
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:35:33	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Pro_Questionnair Visit: WEEK 16 Entered By: Melissa Zeis	1 of 6  Section Date: 12-12-2007 Entry Time: 12-12-2007 16:35:33 Last Modification Time: Page number: 47	Blank? Y  Section Status: Created
PRO QUESTIONNAIRES With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?		
YES / NO		

Section: Hdyf_Oral_Health Visit: WEEK 16 Entered By: Melissa Zeis	2 of 6  Section Date: 12-12-2007 Entry Time: 12-12-2007 16:35:33 Last Modification Time: Page number: 47	Blank? Y  Section Status: Created
HDYF? / ORAL HEALTH QUESTIONS INQUIRY		
Oral Health Questions		
Actual Time	HDYF Performed?	Performed?      Comments

Section: Vital Visit: WEEK 16 Entered By: Melissa Zeis	3 of 6  Section Date: 12-12-2007 Entry Time: 12-12-2007 16:35:33 Last Modification Time: Page number: 47	Blank? Y  Section Status: Created
VITAL SIGNS		
Actual Time	Blood Pressure Systolic      Diastolic	Pulse      Respiratory Rate      Oral Temperature      Unit xxx.x
Comments		

Section: Expired_Carbon_M Visit: WEEK 16	4 of 6  Section Date: 12-12-2007	Blank? Y  Section Status: Created
---	--	---

# CRI Report for Study E627022

Patient: 3019

CRF: Week 16

Visit: WEEK 16

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 19

Document #: R169647413

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:33

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:33

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:33

Last Modification Time:

Page number: 48

## STUDY PRODUCT DISPENSATION

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

# CRI Report for Study E6270229



Patient: 3019  
 CRF: Week 18  
 Visit: WEEK 18  
 Entered By: Melissa Zeis  
 Discrepancies: None  
 Approval Status: Not Approved  
 Verification: Not Verified  
 Comment:

Site: CDB\_001  
 Blank? Y  
 Visit Date: 12-12-2007  
 Entry Time: 12-12-2007 16:35:41  
 Modification Time:  
 Approval Time:  
 Verification Time:

Investigator: CDB\_001  
 CRF Page #: 20  
 Document #: R169647513  
 CRF Status: Created  
 Approver:  
 Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:41	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:41	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:41	
		Last Modification Time:	
		Page number: 49	
VITAL SIGNS			
Actual Time	Blood Pressure	Oral Temperature	Unit
	Systolic Diastolic	xxx.x	
Comments	Pulse	Respiratory Rate	

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:41	
		Last Modification Time:	

# CRF Report for Study E627022

Patient: 3019

CRF: Week 18

Visit: WEEK 18

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 20

Document #: R169647513

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:41

Last Modification Time:

Page number: 50

## STUDY PRODUCT DISPENSATION

Actual Time

Product Dispensed

Flavor

Amount Dispensed

# CRI Report for Study E6270229

Patient: 3019  
 CRF: Week 20  
 Visit: WEEK 20  
 Entered By: Melissa Zeis  
 Discrepancies: None  
 Approval Status: Not Approved  
 Verification: Not Verified  
 Comment:

Site: CDB\_001  
 Blank? Y  
 Visit Date: 12-12-2007  
 Entry Time: 12-12-2007 16:35:48  
 Modification Time:  
 Approval Time:  
 Verification Time:

Investigator: CDB\_001  
 CRF Page #: 21  
 Document #: R169647613  
 CRF Status: Created  
 Approver:  
 Verifier:

Section: Pro_Questionnair	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:48	
		Last Modification Time:	
		Page number: 51	
<b>PRO QUESTIONNAIRES</b> With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed? <span style="float: right;">YES / NO</span>			

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:48	
		Last Modification Time:	
		Page number: 51	
<b>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</b> Oral Health Questions			
Actual Time	HDYF Performed?	Performed?	Comments

Section: Vital	3 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:48	
		Last Modification Time:	
		Page number: 51	
<b>VITAL SIGNS</b>			
Actual Time	Blood Pressure	Pulse	Respiratory Rate
	Systolic      Diastolic		Oral Temperature xxx.x
			Unit
Comments			

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 12-12-2007	

# CRI Report for Study E627022

Patient: 3019

CRF: Week 20

Visit: WEEK 20

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 21

Document #: R169647613

Section: Expired\_Carbon\_M 4 of 6

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:48

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:48

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: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:35:48

Last Modification Time:

Page number: 52

## STUDY PRODUCT DISPENSATION

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



# CRI Report for Study E6270229

Patient: 3019

CRF: Week 22

Visit: WEEK 22

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:35:56

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 22

Document #: R169647713

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:56	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:56	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:56	
		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: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:35:56	
		Last Modification Time:	

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 22

Visit: WEEK 22

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 22

Document #: R169647713

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

Section: Study_Prod_Dispe	5 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22	Section Date: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:35:56		
Last Modification Time:			
Page number: 54			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:36:04

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 23

Document #: R169647813

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:04	
		Last Modification Time:	
		Page number: 55	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES / NO	

Section: Urine_Drug	2 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:04	
		Last Modification Time:	
		Page number: 55	
Drug Screen			
Date	Drug Screen Result		

Section: Alcohol_Screen	3 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:04	
		Last Modification Time:	
		Page number: 55	
Alcohol Screen			
Date	Breathalyzer Result		

Section: Preg_Test	4 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:04	
		Last Modification Time:	
		Page number: 55	
Pregnancy Test			

# CRF Report for Study E627022

Patient: 3019

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 23

Document #: R169647813

Section: Preg_Test	4 of 12
Date	Result

Section: Urine_Coll	5 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:36:04		
	Last Modification Time:		
	Page number: 55		
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
			Stop Time
		Total Volume	Comments

Section: ECG	6 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:36:04		
	Last Modification Time:		
	Page number: 56		
12-LEAD ELECTROCARDIOGRAM REPORT			
Actual Time	Ventricular Heart Rate		
	Cardiac Cycle Measurements		
PR Interval	QRS Duration	QT Interval	QTc Interval
ECG INTERPRETATION:			
Comments (related to abnormal, CS findings only):			

Section: Hdvf Oral Health	7 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:36:04		
	Last Modification Time:		
	Page number: 57		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Date	Actual Time	HDYF Performed?	Oral Health Questions Performed?
			Comments

Section: Vital	8 of 12	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)	Section Date: 12-12-2007		
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:36:04		
	Last Modification Time:		

# CRF Report for Study E6270229

Patient: 3019

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 23

Document #: R169647813

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

Section: Oral_Health_Exam		9 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007		Entry Time: 12-12-2007 16:36:04			
Entered By: Melissa Zeis		Last Modification Time:		Page number: 57			
ORAL HEALTH EXAMINATION							
Date	Procedure		Relevant Findings?*			Findings	

Section: Phys_Exam		10 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007		Entry Time: 12-12-2007 16:36:04			
Entered By: Melissa Zeis		Last Modification Time:		Page number: 58			
PHYSICAL EXAMINATION							
Date	Code Number	Code	Relevant Findings?			Findings	

Section: Weight_Height		11 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007		Entry Time: 12-12-2007 16:36:04			
Entered By: Melissa Zeis		Last Modification Time:		Page number: 58			
WEIGHT & HEIGHT							
Date	Weight xxx.x	Unit	Height xxx.x	Unit			

Section: Lab_Eval		12 of 12		Blank? Y		Section Status: Created	
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007		Entry Time: 12-12-2007 16:36:04			
Entered By: Melissa Zeis							

# CRI Report for Study E6270229

Patient: 3019

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 23

Document #: R169647813

Section: Lab\_Eval

12 of 12

Last Modification Time:

Page number: 59

## Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

No, specify

Requisition Number 1

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

(Yes, specify below)

Requisition Number

Test Name

H/L

Lab ID

Lab Name

# CRI Report for Study E627022

Patient: 3019

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:36:14

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 24

Document #: R169647913

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:14	
		Last Modification Time:	
		Page number: 59	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:14	
		Last Modification Time:	
		Page number: 59	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
			Comments

Section: Blood_Samp_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:14	
		Last Modification Time:	
		Page number: 59	
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:14	
		Last Modification Time:	
		Page number: 60	
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

# CRI Report for Study E627022

Patient: 3019  
CRF: Week 24-2 (Eos)  
Visit: WEEK 24 (EOS)

Site: CDB\_001  
Blank? Y  
Visit Date: 12-12-2007

Investigator: CDB\_001  
CRF Page #: 24  
Document #: R169647913

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

Section: Proventil_Admin	5 of 11	Blank? Y	Section Date: 12-12-2007	Section Status: Created
Visit: WEEK 24 (EOS)		Entry Time: 12-12-2007 16:36:14		
Entered By: Melissa Zeis		Last Modification Time:		
		Page number: 60		
PROVENTIL ADMINISTRATION				
Date	Actual Time of Proventil Administration	Amount Administered		Comments

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:14	
		Last Modification Time:	
		Page number: 60	
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 24 (EOS)		Section Date: 12-12-2007	
Entered By: Melissa Zeis		Entry Time: 12-12-2007 16:36:14	
		Last Modification Time:	
		Page number: 61	
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION			
Scheduled Collection		Number of Study	
Timepoint	Start Date	Tobacco-Heating	
	Start Time	Cigarettes	Weight of
	Stop Date	Collected	Cigarettes Collected
	Stop Time		Any Product
			Deviation?
			If yes, # of other
			Brand
			Comments

Section: Used_Study_Snus	8 of 11	Blank? Y	Section Date: 12-12-2007	Section Status: Created
Visit: WEEK 24 (EOS)		Entry Time: 12-12-2007 16:36:14		
Entered By: Melissa Zeis				



# CRI Report for Study E6270220

Patient: 3019

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 24

Document #: R169647913

Section: Used\_Study\_Snus 8 of 11

Last Modification Time:

Page number: 62

## USED STUDY SNUS COLLECTION

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

Section: Used\_Study\_Bum 9 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:36:14

Last Modification Time:

Page number: 63

## USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used\_Butt\_Measur 10 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:36:14

Last Modification Time:

Page number: 64

## USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

Section: Used\_Butt\_Measur 11 of 11

Blank? Y

Section Status: Created

Visit: WEEK 24 (EOS)

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:36:14

Last Modification Time:

Page number: 65

## USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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

# CRF Report for Study E6270220

Patient: 3019

CRF: Week 24-3

Visit: WEEK 24 (EOS)

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:36:21

Modification Time: 10-01-2008 17:56:37

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 25

Document #: R169648013

CRF Status: Entry Complete

Approver:

Verifier:

Section: Unused\_Study\_Pro

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:36:21

Last Modification Time: 10-01-2008 17:56:37

Page number: 65A

## Unused Study Product Returned

### Amount Returned

Date	Actual Time	Product Returned	Flavor	Packs	Individual Cigarettes / pouches
30-05-2007	UNK	SNUS	FROST	0	52
30-05-2007	UNK	SNUS	SPICE	0	59
30-05-2007	UNK	SNUS	ORIGINAL	0	58

# CRI Report for Study E6270220

Patient: 3019

CRF: Precon\_Med

Visit: PRECON\_MEDS

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? N

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:36:28

Modification Time: 11-01-2008 10:00:03

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 26

Document #: R169648113

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pre\_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON\_MEDS

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:36:28

Last Modification Time: 11-01-2008 08:47:04

Page number: 66

## Previous and Concomitant Medications

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

YES

Seq #	Drug Name	Indication	Dose / Unit	Route	Specify	Freq	Specify	Start Date	Stop Date/Ongoing
1	NUVA RING	CONTRACEPTIVE	UNK	OTH		OTH		00-02-2007	ONGOING
2	IBUPROFEN	MENSTRUAL CRAMPS	400 MG	PO		PRN		00-00-1989	ONGOING



# CRI Report for Study E627022

Patient: 3019

CRF: Ecg\_Unscheduled

Visit: ECG\_UNSCHEDED

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Investigator: CDB\_001

CRF Page #: 28

Document #: R169648313

CRF Status: Created

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:36:44

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: ECG	Blank? Y	Section Status: Created
Visit: ECG_UNSCHEDED	Section Date: 12-12-2007	
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:36:44	
	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

# CRI Report for Study E627022

Patient: 3019

CRF: Lab\_Unscheduled

Visit: LAB\_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:36:52

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 29

Document #: R169648413

CRF Status: Created

Approver:

Verifier:

Section: Lab_Eval	Blank? Y	Section Status: Created
Visit: LAB_UNSCHE	Section Date: 12-12-2007	
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:36:52	
	Last Modification Time:	
	Page number: 69	

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

# CRI Report for Study E627022

Patient: 3019

CRF: Vital\_Unscheduled

Visit: VITAL\_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:37:00

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 30

Document #: R169648513

CRF Status: Created

Approver:

Verifier:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL\_UNSCHE

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:37:00

Last Modification Time:

Page number: 70

## UNSCHEDULED VITAL SIGNS

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

# CRI Report for Study E6270229

Patient: 3019

CRF: Stdy\_Prdt\_Dis\_Unscheduled

Visit: STDY\_PRDT\_UNSCHE

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:37:09

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 31

Document #: R169648613

CRF Status: Created

Approver:

Verifier:

Section: Study\_Prod\_Dispe

Blank? Y

Section Status: Created

Visit: STDY\_PRDT\_UNSCHE

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:37:09

Last Modification Time:

Page number: 71

## UNSCHEDULED STUDY PRODUCT DISPENSATION

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



# CRI Report for Study E627022

Patient: 3019

CRF: Expired\_Co2\_Unscheduled

Visit: EXPIRED\_CO2\_UNSC

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:37:15

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 32

Document #: R169648713

CRF Status: Created

Approver:

Verifier:

Section: Expired_Carbon_M	Blank? Y	Section Status: Created
Visit: EXPIRED_CO2_UNSC	Section Date: 12-12-2007	
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:37:15	
	Last Modification Time:	
	Page number: 72	
UNSCHEDULED EXPIRED CARBON MONOXIDE		
Date	Actual Time	ECO Level (ppm)
		%COHb
		Comments

# CRI Report for Study E627022



Patient: 3019	Site: CDB_001	Investigator: CDB_001
CRF: Oral_Health_Unscheduled	Blank? Y	CRF Page #: 33
Visit: ORAL_HEALTH_UNSC	Visit Date: 12-12-2007	Document #: R169648813
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:37:24	CRF Status: Created
Discrepancies: None	Modification Time:	Approver:
Approval Status: Not Approved	Approval Time:	Verifier:
Verification: Not Verified	Verification Time:	
Comment:		

Section: Oral_Health_Exam	Blank? Y	Section Status: Created
Visit: ORAL_HEALTH_UNSC	Section Date: 12-12-2007	
Entered By: Melissa Zeis	Entry Time: 12-12-2007 16:37:24	
	Last Modification Time:	
	Page number: 73	

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

# CRI Report for Study E627022

Patient: 3019

CRF: Spirometry\_Unscheduled

Visit: SPIRO\_TEST\_UNSCH

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB\_001

Blank? Y

Visit Date: 12-12-2007

Entry Time: 12-12-2007 16:37:53

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB\_001

CRF Page #: 34

Document #: R169648913

CRF Status: Created

Approver:

Verifier:

Section: Pre\_Bronch\_Spir

Blank? Y

Section Status: Created

Visit: SPIRO\_TEST\_UNSCH

Section Date: 12-12-2007

Entered By: Melissa Zeis

Entry Time: 12-12-2007 16:37:53

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: 3019  
CRF: Study\_Completion  
Visit: STUDY\_COMP  
Entered By: Melissa Zeis  
Discrepancies: None  
Approval Status: Not Approved  
Verification: Not Verified  
Comment:

Site: CDB\_001  
Blank? N  
Visit Date: 12-12-2007  
Entry Time: 12-12-2007 16:37:59  
Modification Time: 12-12-2007 16:38:35  
Approval Time:  
Verification Time:

Investigator: CDB\_001  
CRF Page #: 35  
Document #: R169649013  
CRF Status: Entry Complete

Approver:  
Verifier:

Section: Study\_Comp  
Visit: STUDY\_COMP  
Entered By: Melissa Zeis

Blank? N  
Section Date: 12-12-2007  
Entry Time: 12-12-2007 16:37:59  
Last Modification Time: 12-12-2007 16:38:35  
Page number: 75

Section Status: Entry Complete

Study Completion  
Did the subject complete the study? NO  
Date the subject completed OR withdrew from the study: 30-05-2007  
Reason for Withdrawal CONSENT

Specify  
Investigator Comments  
Principal Investigator

Date 23 JAN 2008

**Covance CLS**

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

ACCESSION NO. N746068

Page 1 of 3

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 02-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## SCREEN CHEMISTRY PANEL

Total Bili	0.4	0.2-1.2 mg/dL
Alk Phos	57	31-106 U/L
ALT (SGPT)	18	6-34 U/L
AST (SGOT)	16	9-34 U/L
GGT	19	4-49 U/L
LDH	140	53-234 U/L
Urea Nitr	10	4-24 mg/dL
Creatinine	0.8	0.4-1.1 mg/dL
Glucose	87	70-115 mg/dL
Uric Acid	3.7	2.1-7.2 mg/dL
Calcium	9.6	8.3-10.6 mg/dL
Phosphorus	3.6	2.2-5.1 mg/dL
Total Prot	7.0	6.1-8.4 g/dL
Albumin	4.0	3.3-4.9 g/dL
Sodium	142	132-147 mEq/L
Potassium	4.7	3.4-5.4 mEq/L
Chloride	106	94-112 mEq/L
Triglycer	214	39-176 mg/dL
Cholest	217	141-240 mg/dL

*4 May 2007*

[ ]

[ ]

*Jul Farmer*  
Investigator Signature:

*08 MAY 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

B17177

*QC'd LB 22 MAY 2007*  
(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N746068

Page 2 of 3

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 02-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMATOLOGY &amp; DIFFERENTIAL PANEL

HGB	12.8	11.6-16.4 g/dL
HCT	39	34-48 %
RBC	4.4	4.1-5.6 x10 <sup>6</sup> /uL
MCV	87	79-98 fL
MCH	29	26-34 pg
MCHC	33	31-38 g/dL
RDW	12.9	12.0-15.0 %
RBC Morph	Normocytic	
WBC	7.92	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	4.66	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	2.24	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.81	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.16	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.06	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	58.8	40.5-75.0 %
Lymphocyte	28.3	15.4-48.5 %
Monocytes	10.2	2.6-10.1 %
Eosinophil	2.1	0.0-6.8 %
Basophils	0.7	0.0-2.0 %
Platelets	304	140-400 x10 <sup>3</sup> /uL

[ ]

[ ]

Investigator Signature:

08 MAY 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

B17177

QC4 SB 22 MAY 2007 (INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N746068

Page 3 of 3

**INVESTIGATOR: (B17177)**

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

**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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 02-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

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 1.021

1.003-1.035

pH 6.0

5.0-8.0

Protein Negative

Ref Rng: Negative

Glucose Normal

Ref Rng: Normal

Ketones Negative

Ref Rng: Negative

Bilirubin Negative

Ref Rng: Negative

Urobilin Normal

Ref Rng: Normal

Blood Negative

Ref Rng:

Negative-Trace

Nitrite Negative

Ref Rng: Negative

Leuk Est Negative

Ref Rng: Negative

Microscop Positive

**CELLULAR ELEMENTS**

WBC 1

0-12 /HPF

Squam Epi 2

0-3 /HPF

**MISCELLANEOUS ELEMENTS**

Mucous Present

Ref Rng: Not present

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

B17177

QC'd SB 22 May 2007 (INV)

**Covance CLS**

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

ACCESSION NO. N746068

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

## SPONSOR REPORT TO:

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

## Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 02-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## TOTAL IRON

Total Iron 120 30-160 ug/dL

## FOLLICLE STIMULATING HORMONE

FSH 6.0

## Follicular:

4.0-13.0 mIU/mL

## Mid-Cycle:

5.0-22.0 mIU/mL

## Luteal:

2.0-13.0 mIU/mL

## Postmenopausal:

20.0-138.0 mIU/mL

## HEPATITIS A ANTIBODY-IGM

HepA IgMAb Negative No Ref Rng

*04 May 2007*

*Frank Farmer*  
Investigator Signature:

*08 MAY 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

B17177

*QC'd JB 22 May 2007*



**Covance CLS**

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

ACCESSION NO. N746068

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 02-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2

Non-Reactive

Reference Range:  
Non-Reactive

*4 MAY 2007*



Investigator Signature:

*08 MAY 2007*  
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

B17177

*QC'd 1B 02 MAY 2007 (INV)*

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N746068

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.

c/o Melissa Zeis

Covance-Daytona

1900 Mason Ave

Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 02-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM

Negative

Ref Rng: Negative

*4 MAY 2007*

*[Signature]*  
Investigator Signature:

*10 MAY 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

B17177

*QC'd SB 22 MAY 2007 (INV)*

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. N746068

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 02-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

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

*Ry 11 May 2007*

  
Investigator Signature:

*10 MAY 2007*  
Date:

B17177

(INV)

**Covance CLS**

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

ACCESSION NO. N746068

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

COLLECTION TIME: 12:22 DATE: 30-Apr-2007

DATE RECEIVED IN LABORATORY: 01-May-2007

DATE REPORTED BY LABORATORY: 03-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

HEPATITIS B SURFACE ANTIGEN

HBSAG

Negative

No Ref Rng

HEPATITIS C VIRUS ANTIBODY

ANTI-HCV

Negative

No Ref Rng

HEPATITIS B SURFACE ANTIBODY

#1 HBSAB

EX Positive

No Ref Rng

[ ]

[ ]

ESTRADIOL

Estradiol

4.2

pg/mL

See Inv. Manual

*Awaiting documentation  
of Hep Vaccine.*  
*P. 8/11/07*

Note #1 - Result verified by repeat analysis

Investigator Signature:

*14 MAY 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

B17177

*QC'd JB 22 May 2007 (INV)*

**Covance CLS**

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

**ALERT FAX REPORT**

Sponsor : R J Reynolds Tobacco Co. Investigator Name: Frank Farmer, Jr., M.D.  
Protocol : 6270-229 Investigator ID : 3

Patient ID : S3068 Alert Recipient : Melissa Zeis  
Patient Initials : (b) Alert Fax Number : 1-386-274-1258  
Patient Sex : F  
Patient DOB : (b) (6)

Visit Description: Screen  
Accession Number : N746068

Collection Date : 30-APR-2007  
Collection Time : 12:22

-----  
**HEPATITIS B SURFACE ANTIBODY**

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

Flag Key(s)  
EX Exclusion

*subject has documented  
of Hepatitis B vaccination.*  
*JH*  
*14 MAY 2007*

QCID JB 22 MAY 2007

**Covance CLS**

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

ACCESSION NO. 0299955

Page 1 of 1

## INVESTIGATOR: (B20476)

Frank Farmer, Jr., M.D.  
c/o Deborah Jacobsen  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER: R3019

PATIENT INITIALS: (b)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 21-Jan-2008

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

OXIDIZED LDL

OxidizeLDL

106

30-110 U/L



Investigator Signature:

23 JAN 2008  
Date:

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

B20476

(INV)



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. P205169

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave

Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER: R3019

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:23 DATE: 23-May-2007

DATE RECEIVED IN LABORATORY: 26-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## URINE CREATININE, 24 HR

U24h Creat	1767	H	600-1600 mg/24hr
UAlq24Crea	57.0		mg/dL No Ref Rng

[ ]

[ ]

## ELAPSED DATE AND TIME, 24HR

Elpsd D&amp;T 1440 min

## 24 HR COLLECTION INFORMATION

Start Date	23-May-2007
Start Time	15:23
Stop Date	24-May-2007
Stop Time	15:23

*re urine 2007*

## TOTAL 24HR URINE VOLUME

Total Vol. 3100 mL

*Frank Farmer*  
Investigator Signature:

*30 MAY 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

B17177

*QC DO*  
*06-Jun 2007*

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0299955

Page 1 of 1

## INVESTIGATOR: (B20476)

Frank Farmer, Jr., M.D.  
c/o Deborah Jacobsen  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER: R3019

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 15-Jun-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No


sICAM-1

sICAM-1

241

115-306 ng/mL

*18 Jun 2007*

  
Investigator Signature:

*18 JUN 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

B20476

(INV)



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0299955

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed

*24 May 2007*

*Frank Farmer*  
Investigator Signature:

*30 MAY 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

B17177

*QC DD*  
*06-Jun-2007*

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0299955

Page 1 of 1

**INVESTIGATOR: (B17177)**

Frank Farmer, Jr., M.D.

c/o Melissa Zeis

Covance-Daytona

1900 Mason Ave

Daytona Beach, FL 32117

**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.: 3

RANDOMIZATION NUMBER: R3019

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**HOMOCYSTEINE**

\*1 HCY

5.79

3.36-20.44 umol/L

*Handwritten:*  
24 MAY 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.

*Handwritten Signature*  
Investigator Signature:

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

*Handwritten:*  
30 MAY 2007  
Date:

B17177 QC DD  
06-Jun-2007  
(INV)

**Covance CLS**

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

ACCESSION NO. 0299955

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3019

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: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## LIPID PANEL

Triglycer	190	H	39-176 mg/dL
Cholest	190		141-240 mg/dL
HDL Dex-S	42		36-77 mg/dL
LDL Chol	110		70-156 mg/dL

[ ]

[ ]

*24 May 2007*

*Frank Farmer*  
Investigator Signature:

*30 MAY 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

B17177

(INV)

*QC 20*  
*06-Jun-2007*

**Covance CLS**

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

ACCESSION NO. 0299955  
Page 1 of 1

INVESTIGATOR: (B17177)  
Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

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.: 3  
RANDOMIZATION NUMBER:  
PATIENT INITIALS: (b) (6)  
VISIT: 2

Week 0  
COLLECTION TIME: 06:34 DATE: 24-May-2007  
DATE RECEIVED IN LABORATORY: 25-May-2007  
DATE REPORTED BY LABORATORY: 25-May-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 30  
SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?  
Yes No

HEMOGLOBIN A1C  
Hgb A1c

5.8

Normals:  
4.3-6.1%  
Stable Diabetics:  
4.2-11.2%

*24 May 2007*

*Jul J...*  
Investigator Signature:

30 MAY 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

B17177

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0299955

Page 1 of 3

**INVESTIGATOR: (B17177)**

Frank Farmer, Jr., M.D.

c/o Melissa Zeis

Covance-Daytona

1900 Mason Ave

Daytona Beach, FL 32117

**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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME:06:34 DATE:24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**CHEMISTRY PANEL**

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	58	31-106 U/L
ALT (SGPT)	18	6-34 U/L
AST (SGOT)	15	9-34 U/L
GGT	19	4-49 U/L
LDH	125	53-234 U/L
Urea Nitr	9	4-24 mg/dL
Creatinine	0.8	0.4-1.1 mg/dL
Glucose	100	70-115 mg/dL
Uric Acid	3.2	2.1-7.2 mg/dL
Calcium	9.3	8.3-10.6 mg/dL
Phosphorus	3.7	2.2-5.1 mg/dL
Total Prot	6.5	6.1-8.4 g/dL
Albumin	3.8	3.3-4.9 g/dL
Sodium	138	132-147 mEq/L
Potassium	4.4	3.4-5.4 mEq/L
Chloride	106	94-112 mEq/L

*Re May 2007*

*Frank Farmer Jr.*  
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

B17177

(INV)

*30 APR 2007*  
*May 2007*  
*OC DD*  
*06-Jun-2007*



**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0299955

Page 2 of 3

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave

Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

## HEMATOLOGY &amp; DIFFERENTIAL PANEL

HGB	12.4	11.6-16.4 g/dL
HCT	37	34-48 %
RBC	4.4	4.1-5.6 x10 <sup>6</sup> /uL
MCV	85	79-98 fL
MCH	29	26-34 pg
MCHC	34	31-38 g/dL
RDW	13.5	12.0-15.0 %
RBC Morph	Normocytic	
WBC	8.21	3.80-10.70 x10 <sup>3</sup> /uL
Neutrophil	4.35	1.96-7.23 x10 <sup>3</sup> /uL
Lymphocyte	3.01	0.91-4.28 x10 <sup>3</sup> /uL
Monocytes	0.64	0.12-0.92 x10 <sup>3</sup> /uL
Eosinophil	0.16	0.00-0.57 x10 <sup>3</sup> /uL
Basophils	0.05	0.00-0.20 x10 <sup>3</sup> /uL
Neutrophil	53.0	40.5-75.0 %
Lymphocyte	36.7	15.4-48.5 %
Monocytes	7.8	2.6-10.1 %
Eosinophil	1.9	0.0-6.8 %
Basophils	0.6	0.0-2.0 %
Platelets	307	140-400 x10 <sup>3</sup> /uL

*24 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

B17177

(INV)

*may 25*  
*30 ATR 2007*  
*QC 25*  
*2007 Jun 06*

**Covance CLS**

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

ACCESSION NO. 0299955  
Page 3 of 3

INVESTIGATOR: (B17177)  
Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

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.: 3  
RANDOMIZATION NUMBER:  
PATIENT INITIALS: (b) (6)  
VISIT: 2

Week 0  
COLLECTION TIME: 06:34 DATE: 24-May-2007  
DATE RECEIVED IN LABORATORY: 25-May-2007  
DATE REPORTED BY LABORATORY: 25-May-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 30  
SCREENING NUMBER: S3068

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	1.008	1.003-1.035
pH	5.5	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative-Trace
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

**CELLULAR ELEMENTS**

Squam Epi 4 0-3 /HPF

**MISCELLANEOUS ELEMENTS**


Mucous Present Ref Rng: Not present

  
Investigator Signature:

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

B17177

(INV)

  
30 APR 2007  
Date:

QC DD  
06 Jun 2007

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0299955

Page 1 of 1

**INVESTIGATOR: (B17177)**

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

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: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

**TOTAL IRON**

Total Iron 87 30-160 ug/dL

**C-REACTIVE PROTEIN**

CRP-HS 0.745 H <=0.287 mg/dL

[ ]

[ ]

**CARBOXYHEMOGLOBIN**

Carboxyhem 5.6 % saturation  
No Ref Rng

*29 May 2007*

*[Signature]*  
Investigator Signature:

*30 MAY 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

B17177

*QC DD*  
*06 Jun 2007*

(INV)



**Covance CLS**

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

ACCESSION NO. 0299955  
Page 1 of 1

INVESTIGATOR: (B17177)  
Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

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.: 3  
RANDOMIZATION NUMBER:  
PATIENT INITIALS: (b) (6)  
VISIT: 2

Week 0  
COLLECTION TIME: 06:34 DATE: 24-May-2007  
DATE RECEIVED IN LABORATORY: 25-May-2007  
DATE REPORTED BY LABORATORY: 25-May-2007  
SEX: F BIRTHDATE: (b) (6) AGE: 30  
SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?  
Yes No

FIBRINOGEN  
Fibrinogen 310 200-400 mg/dL

*24 May 2007*

Investigator Signature:

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

*30 MAY 2007*  
Date:

B17177

*QC DD*  
*06 Jun 2007*

(INV)

**Covance CLS**

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

ACCESSION NO. 0299955

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

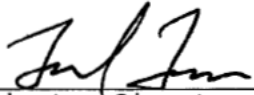
No

URINE CREATININE, SPOT

Rnd Ur Crt 235

mg/dL No Ref Rng

*R*  
*24 May 2007*

  
Investigator Signature:

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

*30 May 2007*  
Date:

B17177

*QC DD*  
*06 Jun 2007*

(INV)

**Covance CLS**

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

ACCESSION NO. 0299955

Page 1 of 1

**INVESTIGATOR: (B17177)**

Frank Farmer, Jr., M.D.  
c/o Melissa Zeis  
Covance-Daytona  
1900 Mason Ave  
Daytona Beach, FL 32117

**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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

Yes

No

sICAM-1

sICAM-1

To follow

*P*  
*24 May 2007*



Investigator Signature:

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

*30 May 2007*

Date:

B17177

*QC DD*  
*06 Jun 2007*

(INV)

**Covance CLS**

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

**LABORATORY REPORT**

ACCESSION NO. 0299955

Page 1 of 1

## INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.

c/o Melissa Zeis

Covance-Daytona

1900 Mason Ave

Daytona Beach, FL 32117

## 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.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:34 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: F BIRTHDATE: (b) (6) AGE: 30

SCREENING NUMBER: S3068

Is this Clinically  
Significant/ Adverse  
Event?

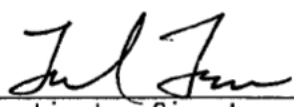
Yes


No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

  
Investigator Signature:

  
24 May 2007  
30 MAY 2007  
Date:

B17177

(INV)

QC DD  
06-Jun-2007