

CRF Report for Study E6270229

Report run by Melissa Zeis at 12-12-2007 16:01:34

Report on Selected Data

Filter: Site CDB_001, Patient 3022

Legend: How different values appear in the report

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

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

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

Page ID: D11453213

/ Covance No. 6270-229

Data Clarification Form

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

Patient#: 3022
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution	
Unused Study Product Returned WEEK 10 Disc ID: 1301169813 Type: MANUAL	14 02AUG07 Closed: N	Disc ID 1289683713 requested a value for the W10 Amount Returned 'Packs'. Resolution provides Amount Returned 'Pouches'. Please provide a response for # of Packs returned.	<input checked="" type="checkbox"/> 0 [] Other: _____	<i>26 Feb 08</i> <i>verified again 17 MAR 08</i>

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 1 of 1

DCF ID: 49345313

Revision #: 0

Page ID: D11229613

/ Covance No. 6270-229

Data Clarification Form

To: Covance CRU Daytona Beach
Investigator: Frank Farmer
Date: 16-JAN-2008

Patient#: 3022
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Oral Health Examination WEEK 0 (BASELINE) Disc ID: 1235931613 Type: MULTIVARIATE	5 23MAY07 Closed: N	Response to 'Relevant Findings?' is Yes for the W0 Oral Health Exam, however findings are not provided.	<input checked="" type="checkbox"/> Findings?=No [] Add finding: _____
Unused Study Product Returned WEEK 10 Disc ID: 1289683713 Type: MANUAL	14 02AUG07 Closed: N	Returned Response to Packs Returned is not provided for the W10 assessment.	____ Packs Confined to be 75 pieces.

Original for # of packs Dm2 012908

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.

F. Farmer
Authorized Personnel Signature

23 JAN 2008
Date

Page ID: D11229713

/ Covance No. 6270-229

Data Clarification Form

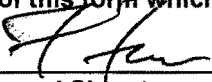
To: Covance CRU Daytona Beach
Investigator: Frank Farmer
Date: 16-JAN-2008

Patient#: 3022
Patient Initials:
Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
Unused Study Product Returned WEEK 24 (EOS) Disc ID: 1289692913 Type: MANUAL	25 12OCT07 Closed: N	Actual Time for the W24 (EOS) Unused Study Product Returned is currently presented as 'BLANK'. Please provide update.	<input checked="" type="checkbox"/> UNK <input type="checkbox"/> NR

Amg
0122805

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

23 JAN 2008
Date

Data Clarification Form

To: Covance CRU Daytona Beach

Investigator: Frank Farmer

Date: 16-JAN-2008

Patient#: 3022

Patient Initials:

Reviewer: Dawn Taylor

Form Name / Visit Name	Page # Date	Questions/Comments	Resolution
24-Hour Urine Collection WEEK 24 (EOS) Disc ID: 1289687513 Type: MANUAL	23 12OCT07 Closed: N	Data fields for the W24/24H Urine Collection are currently populated with 'ND'. Utilizing this dcf, please report these fields consistently across subjects.	<input checked="" type="checkbox"/> ND <input type="checkbox"/> NA
Medical History SCREENING Disc ID: 1289540613 Type: MANUAL	3 11MAY07 Closed: N	As this condition resolved prior to Screening, and leading question indicates 'relevant medical history', please verify if the following Medical History condition should be deleted or maintained: 1-Pneumonia NOTE: If appropriate indicator question will be updated to 'No'	1- <input checked="" type="checkbox"/> Delete <input type="checkbox"/> Maintain

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

CRF Report for Study E6270229

Patient: 3022

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: 11-05-2007

Entry Time: 16-07-2007 14:42:37

Modification Time: 16-07-2007 14:58:05

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 1

Document #: R148770613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Header_Info

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 11-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 14:42:37

Last Modification Time: 16-07-2007 14:58:05

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

CRF Report for Study E6270229

Patient: 3022
 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: 11-05-2007
 Entry Time: 16-07-2007 14:58:06
 Modification Time: 10-12-2007 09:44:40
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 2
 Document #: R148773513
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Inc_Criteria	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:58:06	
		Last Modification Time: 16-07-2007 15:00:34	
		Page number: 2	

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

Section: Inc_Criteria	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:58:06	
		Last Modification Time: 16-07-2007 15:00:34	
		Page number: 20	

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

CRF Report for Study E6270229

Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 11-05-2007

Document #: R148773513

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

Section: Exc_Criteria	3 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:58:06	
		Last Modification Time: 16-07-2007 15:00:34	
		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 of 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: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Screening

Blank? N

CRF Page #: 2

Visit: SCREENING

Visit Date: 11-05-2007

Document #: R148773513

Section: Informed Consent	4 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:58:06	
		Last Modification Time: 16-07-2007 15:00:34	
		Page number: 4	
Informed Consent			
Date the Subject Signed the Smoker Informed Consent Form		11-05-2007	

Section: Elig	5 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:58:06	
		Last Modification Time: 16-07-2007 15:00:34	
		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: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:58:06	
		Last Modification Time: 16-07-2007 15:00:34	
		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: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 14:58:06	
		Last Modification Time: 06-12-2007 13:23:39	
		Page number: 5	
Demographics		Subject Initials	
Date of Birth	Gender	Height	Height Unit
(b) (6)	M	186.9	CM
		xxx.x	
		Weight	Weight Unit
		100.5	KG
		xxx.x	
Ethnicity			

CRF Report for Study E6270229

Patient: 3022

CRF: Screening

Visit: SCREENING

Site: CDB_001

Blank? N

Visit Date: 11-05-2007

Investigator: CDB_001

CRF Page #: 2

Document #: R148773513

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

Section Date: 11-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 14:58:06

Last Modification Time: 06-12-2007 13:25:02

Page number: 5

VITAL SIGNS

Actual Time	Blood Pressure	Pulse	Respiratory Rate	Oral Temperature	Unit
0938	Systolic 134	Diastolic 82	51	16	036.5
				xxx.x	C

Comments

Section: Hdyf_Oral_Health 9 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 11-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 14:58:06

Last Modification Time: 16-07-2007 15:00:34

Page number: 5

HDYF? / ORAL HEALTH QUESTIONS INQUIRY

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

Section: Lab_Eval 10 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 11-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 14:58:06

Last Modification Time: 16-07-2007 15:00:34

Page number: 6

Laboratory Evaluations

Were the scheduled laboratory samples obtained? YES No, specify

Requisition Number 1 N702585

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
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CRF Report for Study E6270229



Patient: 3022
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: 11-05-2007
Entry Time: 16-07-2007 15:00:35
Modification Time: 06-12-2007 13:43:57
Approval Time:
Verification Time:

Investigator: CDB_001
CRF Page #: 3
Document #: R148773813
CRF Status: Entry Complete
Approver:
Verifier:

Section: Preg_Test	1 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35	
		Last Modification Time: 16-07-2007 15:06:48	
		Page number: 6	
Urine Pregnancy Test			
Result			
N/A,			
MALE			
OR			
FEMA			
LE			

Section: Urine_Drug	2 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35	
		Last Modification Time: 16-07-2007 15:06:48	
		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: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35	
		Last Modification Time: 16-07-2007 15:06:48	
		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: 11-05-2007	

CRF Report for Study E6270229



Patient: 3022
CRF: Screening2
Visit: SCREENING

Site: CDB_001
Blank? N
Visit Date: 11-05-2007

Investigator: CDB_001
CRF Page #: 3
Document #: R148773813

Section: Med_Hx 4 of 10

Entered By: Melissa Zeis

Entry Time: 16-07-2007 15:00:35

Last Modification Time: 06-12-2007 13:29:46

Page number: 7

Medical History

Does the subject have any relevant medical history?

YES

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

System	Diagnosis/Procedure	Date of Onset	Date of Resolution/Ongoing
SKIN			
EENT			
BREASTS			
RESP	PNEUMONIA	00-00-1968	00-00-1968
CARDIO			
LYMPH/HEMA			
GASTRO			
GENITO			
MUSCULO			
ENDOCRINE			
NEURO			
IMMUNO			
PSYCH			
ALLERGIC			
OTHER			

Section: ECG 5 of 10

Blank? N

Section Status: Entry Complete

Visit: SCREENING

Section Date: 11-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 15:00:35

Last Modification Time: 16-07-2007 15:06:48

Page number: 8

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time

Ventricular Heart Rate

1010

45

Cardiac Cycle Measurements

PR Interval

QRS Duration

QT Interval

QTc Interval

146

92

474

450

ECG INTERPRETATION:

ANCS

Comments (related to abnormal, CS findings only):

Usual Brand Cig 6 10

N

Entry Complete

CRF Report for Study E6270229

Patient: 3022
CRF: Screening2
Visit: SCREENING

Site: CDB_001
Blank? N
Visit Date: 11-05-2007

Investigator: CDB_001
CRF Page #: 3
Document #: R148773813

Section: Usual_Brand_Cig	6 of 10	Blank?	Section Status:	
Visit: SCREENING		Section Date: 11-05-2007		
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35		
		Last Modification Time: 16-07-2007 15:06:48		
		Page number: 9		

Usual Brand	USUAL BRAND CIGARETTE PACK	DATA	Length
DORAL	Type NON-MENTHOL		LONG 90-105MM
Style ULTRALIGHTS	Pack HARD	How long have these been the subject's usual brand?	UNK months
			10 years

Section: Ftc_Tar_Level	7 of 10	Blank? N	Section Status: Entry Complete	
Visit: SCREENING		Section Date: 11-05-2007		
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35		
		Last Modification Time: 16-07-2007 15:06:48		
		Page number: 9		

FTC TAR LEVEL OF USUAL BRAND
FTC Tar Level (mg) 4.4

Section: Expired_Carbon_M	8 of 10	Blank? N	Section Status: Entry Complete	
Visit: SCREENING		Section Date: 11-05-2007		
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35		
		Last Modification Time: 16-07-2007 15:06:48		
		Page number: 10		

EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
0925	27	4.9	

Section: Best_Baseline_Sp	9 of 10	Blank? N	Section Status: Entry Complete			
Visit: SCREENING		Section Date: 11-05-2007				
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35				
		Last Modification Time: 06-12-2007 13:43:57				
		Page number: 10				

BEST BASELINE SPIROMETRY TEST RESULT						
Actual Time of FEV1/FVC Test	Testing Position	FEV1 L	FEV 1 Predicted (%)	FVC L	FVC Predicted (%)	Comments

CRF Report for Study E6270229



Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Screening2

Blank? N

CRF Page #: 3

Visit: SCREENING

Visit Date: 11-05-2007

Document #: R148773813

Section: Best_Baseline_Sp	9 of 10				
1029	STANDING	3.41	80	3.96	71

Section: lrvs_Training	10 of 10	Blank? N	Section Status: Entry Complete
Visit: SCREENING		Section Date: 11-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:00:35	
		Last Modification Time: 16-07-2007 15:06:48	
		Page number: 10	
IVRS TRAINING			
Did Subject receive training on the Daily Call-In Diary (IVRS)?			
YES			

CRF Report for Study E6270229



Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Week-2

Blank? N

CRF Page #: 4

Visit: WEEK -2

Visit Date: 21-05-2007

Document #: R148776313

Entered By: Melissa Zeis

Entry Time: 16-07-2007 15:07:02

CRF Status: Entry Complete

Discrepancies: None

Modification Time: 16-07-2007 15:07:28

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Usual_Brand_Coll	Blank? N	Section Status: Entry Complete												
Visit: WEEK -2	Section Date: 21-05-2007													
Entered By: Melissa Zeis	Entry Time: 16-07-2007 15:07:02													
	Last Modification Time: 16-07-2007 15:07:28													
	Page number: 11													
<table><thead><tr><th>USUAL BRAND</th><th>CIGARETTE COLLECTION TRAINING</th><th></th></tr></thead><tbody><tr><td>1. Did subject receive foam block?</td><td></td><td>YES</td></tr><tr><td>2. Did subject receive training on usual brand collection?</td><td></td><td>YES</td></tr><tr><td>3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?</td><td></td><td>YES</td></tr></tbody></table>			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
USUAL BRAND	CIGARETTE COLLECTION TRAINING													
1. Did subject receive foam block?		YES												
2. Did subject receive training on usual brand collection?		YES												
3. Was subject provided usual brand cigarettes for Week 0 cigarette butt collection?		YES												

CRF Report for Study E6270229



Patient: 3022

CRF: Week 0 Baseline

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 23-05-2007

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

Modification Time: 10-12-2007 09:44:40

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5

Document #: R148776513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnair	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 15:07:29	
		Last Modification Time: 16-07-2007 15:10:31	
		Page number: 12A	

PRO QUESTIONNAIRES		
Date		YES / NO
23-05-2007	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES

Section: Urine_Drug	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:07:29	
		Last Modification Time: 16-07-2007 15:10:31	
		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 15:07:29	
		Last Modification Time: 16-07-2007 15:10:31	
		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 15:07:29	
		Last Modification Time: 16-07-2007 15:10:31	
		Page number: 12A	

CRF Report for Study E6270229

Patient: 3022

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 #: R148776513

Section: Preg_Test		4 of 11
Pregnancy Test		
Date	Result	
23-05-2007	N/A, MALE OR FEMA LE	

Section: Urine_Coll		5 of 11	Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007				
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:07:29				
		Last Modification Time: 09-12-2007 12:13:30				
		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	1550	NA	NA	NA	
0 HOUR TO 24 HOURS	23-05-2007	1550	24-05-2007	1550	2450	

Section: Hdyf_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 15:07:29				
		Last Modification Time: 16-07-2007 15:10:31				
		Page number: 13.1				
HDYF? INQUIRY						
Date	Actual Time	HDYF Performed?		Comments		
24-05-2007	0530	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 15:07:29					
		Last Modification Time: 16-07-2007 15:10:31					
		Page number: 13.1					
VITAL SIGNS							
		Blood Pressure		Oral			
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature Unit	
23-05-2007	1601	126	74	71	16	37.0 C	

CRF Report for Study E6270229

Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Week 0 Baseline

Blank? N

CRF Page #: 5

Visit: WEEK 0 (BASELINE)

Visit Date: 23-05-2007

Document #: R148776513

Section: Vital	7 of 11	
Comments		xxx.x

Section: Oral_Health_Exam	8 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:07:29	
		Last Modification Time: 06-12-2007 13:46:58	
		Page number: 13.1	
ORAL HEALTH EXAMINATION			
Date 24-05-2007	Procedure ORAL HEALTH QUESTIONS PERFORMED EVIDENCE OF LEUKOPLAKIA OTHER ORAL KERATOSIS	Relevant Findings? YES NO NO	Findings

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 15:07:29	
		Last Modification Time: 06-12-2007 13:48:09	
		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	NE

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



Patient: 3022

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 #: R148776513

Section: Weight_Height 10 of 11

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Section Date: 23-05-2007

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

Last Modification Time: 06-12-2007 13:49:55

Page number: 14.1

WEIGHT & HEIGHT

Date	Weight	Unit	Height	Unit
23-05-2007	099.4	KG	ND	
	xxx.x		xxx.x	

Section: Lab_Eval 11 of 11

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Entered By: Melissa Zeis

Section Date: 23-05-2007

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

Last Modification Time: 06-12-2007 13:57:44

Page number: 15.1

Laboratory Evaluations

Date

24-05-2007

Were the scheduled laboratory samples obtained?

YES

No, specify

Requisition Number 1

P060627

Requisition Number 2 (if applicable)

Were there any clinically significant labs?

NO

(Yes, specify below)

23-05-2007

YES

P205167

NO

Requisition Number

Test Name

H/L

Lab ID

Lab Name

CRF Report for Study E6270229



Patient: 3022

CRF: Week 0 2baseline

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 15:10:32

Modification Time: 06-12-2007 14:04:31

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5.1

Document #: R148777513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:10:32	
		Last Modification Time: 16-07-2007 15:18:43	
		Page number: 15.1	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
24-05-2007	0626		

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 15:10:32	
		Last Modification Time: 16-07-2007 15:18:43	
		Page number: 15.1	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
24-05-2007	1122	30	5.4
Comments			

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 15:10:32	
		Last Modification Time: 16-07-2007 15:18:43	
		Page number: 15.1	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
24-05-2007	1126		

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 15:10:32	
		Last Modification Time: 16-07-2007 15:18:43	
		Page number: 16.1	

CRF Report for Study E6270229

Patient: 3022

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 #: R148777513

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	1359	STANDI	3.89	92	4.54	82	
		NG					

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 15:10:32	
	Last Modification Time:	16-07-2007 15:18:43	
	Page number:	16.1	
PROVENTIL ADMINISTRATION			
	Actual Time of Proventil		
Date	Administration	Amount Administered	Comments
24-05-2007	1405	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 15:10:32					
		Last Modification Time: 06-12-2007 14:04:31					
		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	1422	STANDING	3.46	81	4.08	74	

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 15:10:32	
		Last Modification Time: 16-07-2007 15:18:43	
		Page number: 17.1	
Unused Usual Brand Cigarette Pack Collection			
			Yes / No
Date	Does Site have 5 unopened packs of subject's usual brand cigarette to ship to CCLS?		
24-05-2007			YES

CRF Report for Study E6270229

Patient: 3022

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 #: R148777513

Section: Usual_Brand_Butt		8 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007		Entry Time: 16-07-2007 15:10:32			
Entered By: Melissa Zeis		Last Modification Time: 16-07-2007 15:18:43		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	40	NO		
24 HOURS IN-HOUSE	23-05- 2007	1500	24-05-2007	1500	27	NO		

Section: Used_Butt_Measur		9 of 11		Blank? N		Section Status: Entry Complete	
Visit: WEEK 0 (BASELINE)		Section Date: 23-05-2007		Entry Time: 16-07-2007 15:10:32			
Entered By: Melissa Zeis		Last Modification Time: 16-07-2007 15:18:43		Page number: 18.1			

USUAL BRAND CIGARETTE BUTT MEASUREMENT		
Date	Scheduled Collection Period	
23-05-2007	24 HOURS PRIOR TO CHECK-IN	

Cigarette Butt Number	Cigarette Butt Measurement (mm)
1	47
2	41
3	41
4	35
5	43
6	41
7	40
8	38
9	42
10	39
11	38
12	38
13	45
14	38
15	52
16	50
17	40

CRF Report for Study E6270229

Patient: 3022

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 #: R148777513

Section: Used_Butt_Measur 9 of 11

18	41
19	38
20	38
21	42
22	39
23	38
24	40
25	39
26	48
27	51
28	45
29	36
30	40
31	43
32	50
33	39
34	37
35	39
36	44
37	49
38	38
39	45
40	43

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 Zels

Entry Time: 16-07-2007 15:10:32

Last Modification Time: 16-07-2007 15:18:43

Page number: 19.1

USUAL BRAND CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date

Period

24-05-2007

24 HOURS IN-HOUSE

Cigarette Butt Number

Cigarette Butt Measurement (mm)

1	44
2	51
3	45
4	47
5	57
6	48

CRF Report for Study E6270229



Patient: 3022

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 #: R148777513

Section: Used_Butt_Measur	10 of 11
	7 44
	8 51
	9 52
	10 51
	11 50
	12 50
	13 41
	14 46
	15 41
	16 48
	17 54
	18 48
	19 56
	20 52
	21 48
	22 49
	23 35
	24 39
	25 46
	26 36
	27 40

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 15:10:32	
		Last Modification Time: 16-07-2007 15:18:43	
		Page number: 20.1	
RANDOMIZATION			
Date	Actual Time	Randomization Sequence	
24-05-2007	1435	GROUP B	

CRF Report for Study E6270229



Patient: 3022

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: 23-05-2007

Entry Time: 16-07-2007 15:18:44

Modification Time: 09-12-2007 12:16:17

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 5.2

Document #: R148780213

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Prod_Dispe

Blank? N

Section Status: Entry Complete

Visit: WEEK 0 (BASELINE)

Section Date: 23-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 15:18:44

Last Modification Time: 09-12-2007 12:16:17

Page number: 23.1

STUDY PRODUCT DISPENSATION

Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed
24-05-2007	1520	SNUS	ORIGINAL	1
24-05-2007	1520	SNUS	SPICE	1
24-05-2007	1520	SNUS	FROST	1

CRF Report for Study E6270229



Patient: 3022

CRF: Intercurrent_Ill

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 15:20:11

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

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 7

Document #: R148780813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Id_Findings

Blank? N

Section Status: Entry Complete

Visit: INTERCURRENT ILL

Section Date: 23-05-2007

Entered By: Melissa Zeis

Entry Time: 16-07-2007 15:20:11

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

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

Onset

Resolved / Changed

Relationship

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

CRF Report for Study E6270229



Patient: 3022
 CRF: Week 1
 Visit: WEEK 1
 Entered By: Melissa Zeis
 Discrepancies: Active
 Approval Status: Not Approved
 Verification: Not Verified

Site: CDB_001
 Blank? N
 Visit Date: 01-06-2007
 Entry Time: 16-07-2007 15:20:52
 Modification Time: 06-12-2007 14:12:56
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 8
 Document #: R148781613
 CRF Status: Entry Complete

Approver:
 Verifier:

Comment:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 01-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:20:52	
		Last Modification Time: 16-07-2007 15:22:48	
		Page number: 22	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions Performed?	Comments
Actual Time	HDYF Performed?		
1048	YES	YES	

Section: Vital	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 01-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:20:52	
		Last Modification Time: 16-07-2007 15:22:48	
		Page number: 22	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
1105	135	83	54
			Respiratory Rate
			16
			Temperature
			36.6
			xxx.x
			Unit
			C
Comments			

Section: Expired_Carbon_M	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 01-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:20:52	
		Last Modification Time: 16-07-2007 15:22:48	
		Page number: 22	
EXPIRED CARBON MONOXIDE			
	Actual Time	ECO Level (ppm)	%COHb
	1119	2	0.9
Comments			

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

Patient: 3022
CRF: Week 1
Visit: WEEK 1

Site: CDB_001
Blank? N
Visit Date: 01-06-2007

Investigator: CDB_001
CRF Page #: 8
Document #: R148781613

Section: Unused_Study_Pro	4 of 5	Section Date: 01-06-2007
Visit: WEEK 1		Entry Time: 16-07-2007 15:20:52
Entered By: Melissa Zeis		Last Modification Time: 16-07-2007 15:22:48
		Page number: 23

Unused Study Product Returned		Amount Returned	
Product Returned	Flavor	Packs	Individual Cigarettes / pouches
SNUS	ORIGINAL	0	61
SNUS	SPICE	0	60
SNUS	FROST	0	14

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 1		Section Date: 01-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:20:52	
		Last Modification Time: 06-12-2007 14:12:56	
		Page number: 23	

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1123	SNUS	FROST	1

CRF Report for Study E6270229



Patient: 3022
 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: 08-06-2007
 Entry Time: 16-07-2007 15:22:49
 Modification Time: 06-12-2007 14:16:29
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 9
 Document #: R148782213
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Hdyf_Oral_Health		1 of 6	Blank? N	Section Status: Entry Complete	
Visit: WEEK 2		Section Date: 08-06-2007			
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:22:49			
		Last Modification Time: 16-07-2007 15:24:04			
		Page number: 24			
HDYF? / ORAL HEALTH QUESTIONS INQUIRY					
		Oral Health Questions			
Actual Time	HDYF Performed?	Performed?	Comments		
1108	YES	YES			

Section: Vital		2 of 6	Blank? N	Section Status: Entry Complete	
Visit: WEEK 2		Section Date: 08-06-2007			
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:22:49			
		Last Modification Time: 16-07-2007 15:24:04			
		Page number: 24			
VITAL SIGNS					
	Blood Pressure			Oral	
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature
1126	124	84	56	20	36.5
					xxx.x
Unit C					
Comments					

Section: Expired_Carbon_M		3 of 6	Blank? N	Section Status: Entry Complete	
Visit: WEEK 2		Section Date: 08-06-2007			
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:22:49			
		Last Modification Time: 16-07-2007 15:24:04			
		Page number: 24			
EXPIRED CARBON MONOXIDE					
Actual Time	ECO Level (ppm)		%COHb	Comments	
1127	4		1.2		

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



Patient: 3022

CRF: Week 2

Visit: WEEK 2

Site: CDB_001

Blank? N

Visit Date: 08-06-2007

Investigator: CDB_001

CRF Page #: 9

Document #: R148782213

Section: Blood_Samp_Cohb	4 of 6	Section Date: 08-06-2007
Visit: WEEK 2		Entry Time: 16-07-2007 15:22:49
Entered By: Melissa Zeis		Last Modification Time: 16-07-2007 15:24:04
		Page number: 24
Blood Sampling for %COHb		
Actual Time	Comments	
1135		

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 08-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:22:49	
		Last Modification Time: 16-07-2007 15:24:04	
		Page number: 25	
Unused Study Product Returned			
		Amount Returned	
Product Returned	Flavor	Packs	Individual Cigarettes / pouches
SNUS	FROST	0	0

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 2		Section Date: 08-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:22:49	
		Last Modification Time: 06-12-2007 14:16:29	
		Page number: 25	
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1138	SNUS	FROST	2

CRF Report for Study E6270229



Patient: 3022

CRF: Week 4

Visit: WEEK 4

Entered By: Melissa Zeis

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 22-06-2007

Entry Time: 16-07-2007 15:25:15

Modification Time: 06-12-2007 14:17:41

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 10

Document #: R148783513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 22-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:25:15	
		Last Modification Time: 16-07-2007 15:26:52	
		Page number: 26	
<p>PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p>			<p>YES / NO</p> <p>YES</p>

Section: Hdyf_Oral_Health	2 of 6	Blank? N	Section Status: Entry Complete												
Visit: WEEK 4		Section Date: 22-06-2007													
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:25:15													
		Last Modification Time: 16-07-2007 15:26:52													
		Page number: 26													
<p>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%; text-align: center;">Oral Health Questions</td> <td style="width: 40%;"></td> </tr> <tr> <td style="text-align: center;">Actual Time</td> <td style="text-align: center;">HDYF Performed?</td> <td style="text-align: center;">Performed?</td> <td style="text-align: center;">Comments</td> </tr> <tr> <td style="text-align: center;">1132</td> <td style="text-align: center;">YES</td> <td style="text-align: center;">YES</td> <td></td> </tr> </table>						Oral Health Questions		Actual Time	HDYF Performed?	Performed?	Comments	1132	YES	YES	
		Oral Health Questions													
Actual Time	HDYF Performed?	Performed?	Comments												
1132	YES	YES													

Section: Vital	3 of 6	Blank? N	Section Status: Entry Complete																												
Visit: WEEK 4		Section Date: 22-06-2007																													
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:25:15																													
		Last Modification Time: 16-07-2007 15:26:52																													
		Page number: 26																													
<p>VITAL SIGNS</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%; text-align: center;">Blood Pressure</td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%; text-align: center;">Oral</td> <td style="width: 10%;"></td> </tr> <tr> <td style="text-align: center;">Actual Time</td> <td style="text-align: center;">Systolic</td> <td style="text-align: center;">Diastolic</td> <td style="text-align: center;">Pulse</td> <td style="text-align: center;">Respiratory Rate</td> <td style="text-align: center;">Temperature</td> <td style="text-align: center;">Unit</td> </tr> <tr> <td style="text-align: center;">1138</td> <td style="text-align: center;">132</td> <td style="text-align: center;">84</td> <td style="text-align: center;">64</td> <td style="text-align: center;">12</td> <td style="text-align: center;">36.7 xxx.x</td> <td style="text-align: center;">C</td> </tr> <tr> <td colspan="7" style="height: 20px;">Comments</td> </tr> </table>					Blood Pressure				Oral		Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit	1138	132	84	64	12	36.7 xxx.x	C	Comments						
	Blood Pressure				Oral																										
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit																									
1138	132	84	64	12	36.7 xxx.x	C																									
Comments																															

CRF Report for Study E6270229

Patient: 3022
CRF: Week 4
Visit: WEEK 4

Site: CDB_001
Blank? N
Visit Date: 22-06-2007

Investigator: CDB_001
CRF Page #: 10
Document #: R148783513

Section: Expired_Carbon_M	4 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 22-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:25:15	
		Last Modification Time: 16-07-2007 15:26:52	
		Page number: 26	

EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1139	3	1.1	

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 22-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:25:15	
		Last Modification Time: 16-07-2007 15:26:52	
		Page number: 27	

Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches
SNUS	FROST	0	0

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 4		Section Date: 22-06-2007	
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:25:15	
		Last Modification Time: 06-12-2007 14:17:41	
		Page number: 27	

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1145	SNUS	FROST	1
1145	SNUS	ORIGINAL	1

CRF Report for Study E6270229



Patient: 3022
 CRF: Week 6
 Visit: WEEK 6
 Entered By: Melissa Zeis
 Discrepancies: Active
 Approval Status: Not Approved
 Verification: Not Verified
 Comment:

Site: CDB_001
 Blank? N
 Visit Date: 06-07-2007
 Entry Time: 16-07-2007 15:26:53
 Modification Time: 09-12-2007 12:17:11
 Approval Time:
 Verification Time:

Investigator: CDB_001
 CRF Page #: 11
 Document #: R148784313
 CRF Status: Entry Complete
 Approver:
 Verifier:

Section: Hdyf_Oral_Health		1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 6		Section Date: 06-07-2007		
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:26:53		
		Last Modification Time: 16-07-2007 15:28:59		
		Page number: 28		
HDYF? / ORAL HEALTH QUESTIONS INQUIRY				
Oral Health Questions				
Actual Time	HDYF Performed?	Performed?	Comments	
1045	YES	YES		

Section: Expired_Carbon_M		2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 6		Section Date: 06-07-2007		
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:26:53		
		Last Modification Time: 16-07-2007 15:28:59		
		Page number: 28		
EXPIRED CARBON MONOXIDE				
Actual Time	ECO Level (ppm)	%COHb	Comments	
1057	4	1.2		

Section: Vital		3 of 5	Blank? N	Section Status: Entry Complete		
Visit: WEEK 6		Section Date: 06-07-2007				
Entered By: Melissa Zeis		Entry Time: 16-07-2007 15:26:53				
		Last Modification Time: 16-07-2007 15:28:59				
		Page number: 28				
VITAL SIGNS						
Actual Time	Blood Pressure		Pulse	Respiratory Rate	Oral Temperature	Unit
1054	Systolic 137	Diastolic 77	57	16	36.7 xxx.x	C
Comments						

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



Patient: 3022
CRF: Week 6
Visit: WEEK 6

Site: CDB_001
Blank? N
Visit Date: 06-07-2007

Investigator: CDB_001
CRF Page #: 11
Document #: R148784313

Section: Unused_Study_Pro	4 of 5		
Visit: WEEK 6	Section Date: 06-07-2007		
Entered By: Melissa Zeis	Entry Time: 16-07-2007 15:26:53		
	Last Modification Time: 16-07-2007 15:28:59		
	Page number: 29		

Unused Study Product Returned			
		Amount Returned	
Product Returned	Flavor	Packs	Individual Cigarettes / pouches
SNUS	FROST	0	0
SNUS	ORIGINAL	0	0

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 6	Section Date: 06-07-2007		
Entered By: Melissa Zeis	Entry Time: 16-07-2007 15:26:53		
	Last Modification Time: 09-12-2007 12:17:11		
	Page number: 29		

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1120	SNUS	FROST	1
1120	SNUS	ORIGINAL	1

CRF Report for Study E6270229



Patient: 3022

CRF: Week 8

Visit: WEEK 8

Entered By: Christina Breedlove

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 20-07-2007

Entry Time: 20-07-2007 14:11:08

Modification Time: 06-12-2007 14:19:35

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 13

Document #: R149403813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 20-07-2007	
Entered By: Christina Breedlove		Entry Time: 20-07-2007 14:11:08	
		Last Modification Time: 20-07-2007 14:13:58	
		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
			YES

Section: HDYF_Oral_Health	2 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 20-07-2007	
Entered By: Christina Breedlove		Entry Time: 20-07-2007 14:11:08	
		Last Modification Time: 20-07-2007 14:13:58	
		Page number: 30	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions Performed?	Comments
Actual Time	HDYF Performed?		
1121	YES	YES	

Section: Vital	3 of 6	Blank? N	Section Status: Entry Complete			
Visit: WEEK 8		Section Date: 20-07-2007				
Entered By: Christina Breedlove		Entry Time: 20-07-2007 14:11:08				
		Last Modification Time: 20-07-2007 14:13:58				
		Page number: 30				
VITAL SIGNS						
	Blood Pressure		Oral			
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit
1126	139	080	073	20	036.8	C
					xxx.x	
Comments						

CRF Report for Study E6270229



Patient: 3022
CRF: Week 8
Visit: WEEK 8

Site: CDB_001
Blank? N
Visit Date: 20-07-2007

Investigator: CDB_001
CRF Page #: 13
Document #: R149403813

Section: Expired_Carbon_M	4 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 20-07-2007	
Entered By: Christina Breedlove		Entry Time: 20-07-2007 14:11:08	
		Last Modification Time: 20-07-2007 14:13:58	
		Page number: 30	

EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1130	3	01.1	

Section: Unused_Study_Pro	5 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 20-07-2007	
Entered By: Christina Breedlove		Entry Time: 20-07-2007 14:11:08	
		Last Modification Time: 20-07-2007 14:13:58	
		Page number: 31	

Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches
SNUS	FROST	0	0
SNUS	ORIGINAL	0	41

Section: Study_Prod_Dispe	6 of 6	Blank? N	Section Status: Entry Complete
Visit: WEEK 8		Section Date: 20-07-2007	
Entered By: Christina Breedlove		Entry Time: 20-07-2007 14:11:08	
		Last Modification Time: 06-12-2007 14:19:35	
		Page number: 31	

STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1143	SNUS	FROST	2

CRF Report for Study E6270229



Patient: 3022

CRF: Week 10

Visit: WEEK 10

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 02-08-2007

Entry Time: 06-12-2007 14:27:01

Modification Time: 09-12-2007 12:35:15

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 14

Document #: R169064513

CRF Status: Entry Complete

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 02-08-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 14:27:01	
		Last Modification Time: 09-12-2007 12:35:15	
		Page number: 32	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments
1252	YES	YES	

Section: Expired_Carbon_M	2 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 02-08-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 14:27:01	
		Last Modification Time: 06-12-2007 15:22:02	
		Page number: 32	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments
1311	3	01.1	

Section: Vital	3 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 02-08-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 14:27:01	
		Last Modification Time: 06-12-2007 15:22:02	
		Page number: 32	
VITAL SIGNS			
	Blood Pressure		
Actual Time	Systolic	Diastolic	Pulse
1308	139	075	072
			Respiratory Rate
			20
			Oral Temperature
			036.9
			xxx.x
Unit			
C			
Comments			

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

Patient: 3022

CRF: Week 10

Visit: WEEK 10

Site: CDB_001

Blank? N

Visit Date: 02-08-2007

Investigator: CDB_001

CRF Page #: 14

Document #: R169064513

Section: Unused_Study_Pro	4 of 5	Section Date: 02-08-2007
Visit: WEEK 10		Entry Time: 06-12-2007 14:27:01
Entered By: Christina Breedlove		Last Modification Time: 06-12-2007 15:22:02
Page number: 33		
Unused Study Product Returned		
Product Returned	Flavor	Amount Returned
SNUS	FROST	Packs Individual Cigarettes / pouches
		75

Section: Study_Prod_Dispe	5 of 5	Blank? N	Section Status: Entry Complete
Visit: WEEK 10		Section Date: 02-08-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 14:27:01	
		Last Modification Time: 06-12-2007 15:22:02	
Page number: 33			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed
1330	SNUS	FROST	1

CRF Report for Study E6270229



Patient: 3022

CRF: Week 12

Visit: WEEK 12

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 15:22:29

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 15

Document #: R169069113

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnair	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 34	
PRO QUESTIONNAIRES			
Date	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES / NO	

Section: Urine_Drug	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 34	
Drug Screen			
Date	Drug Screen Result		

Section: Alcohol_Screen	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 34	
Alcohol Screen			
Date	Breathalyzer Result		

Section: Preg_Test	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 34	
Pregnancy Test			

CRF Report for Study E6270229

Patient: 3022

CRF: Week 12

Visit: WEEK 12

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Investigator: CDB_001

CRF Page #: 15

Document #: R169069113

Section: Preg_Test	4 of 11
Date	Result

Section: Urine_Coll	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 34	
24-Hour Urine Collection			
Scheduled Timepoint	Start Date	Start Time	Stop Date
		Stop Time	Total Volume
			Comments

Section: Hdyl_Oral_Health	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 35	
HDYF? INQUIRY			
Date	Actual Time	HDYF Performed?	Comments

Section: Vital	7 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 35	
VITAL SIGNS			
		Blood Pressure	Oral Temperature
Date	Actual Time	Systolic	Diastolic
		Pulse	Respiratory Rate
			Unit
			xxx.x
Comments			

Section: Oral_Health_Exam	8 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:29	
		Last Modification Time:	
		Page number: 35	
ORAL HEALTH EXAMINATION			

CRF Report for Study E6270229



Patient: 3022
CRF: Week 12
Visit: WEEK 12

Site: CDB_001
Blank? Y
Visit Date: 00-00-

Investigator: CDB_001
CRF Page #: 15
Document #: R169069113

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

Section: Phys_Exam	9 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 06-12-2007 15:22:29	
Entered By: Christina Breedlove	Last Modification Time:	Page number: 36	
PHYSICAL EXAMINATION			
Date	Code Number	Code	Relevant Findings?
			Findings

Section: Weight_Height	10 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 06-12-2007 15:22:29	
Entered By: Christina Breedlove	Last Modification Time:	Page number: 36	
WEIGHT & HEIGHT			
Date	Weight xxx.x	Unit	Height xxx.x
			Unit

Section: Lab_Eval	11 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-	Entry Time: 06-12-2007 15:22:29	
Entered By: Christina Breedlove	Last Modification Time:	Page number: 37	
Laboratory Evaluations			
Date			
Were the scheduled laboratory samples obtained?	No, specify		
Requisition Number 1			
Requisition Number 2 (if applicable)			
Were there any clinically significant labs?	(Yes, specify below)		
Requisition Number	Test Name	H/L	Lab ID
			Lab Name

CRF Report for Study E6270229



Patient: 3022

CRF: Week 12(2)

Visit: WEEK 12

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 15:22:35

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 16

Document #: R169069213

CRF Status: Created

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-		
Entered By: Christina Breedlove	Entry Time: 06-12-2007 15:22:35		
	Last Modification Time:		
	Page number: 37		
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	

Section: Expired_Carbon_M	2 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-		
Entered By: Christina Breedlove	Entry Time: 06-12-2007 15:22:35		
	Last Modification Time:		
	Page number: 37		
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
			Comments

Section: Blood_Sampl_Cohb	3 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-		
Entered By: Christina Breedlove	Entry Time: 06-12-2007 15:22:35		
	Last Modification Time:		
	Page number: 37		
Blood Sampling for %COHb			
Date	Actual Time	Comments	

Section: Pre_Bronch_Spir	4 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12	Section Date: 00-00-		
Entered By: Christina Breedlove	Entry Time: 06-12-2007 15:22:35		
	Last Modification Time:		
	Page number: 38		
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT			
Actual Time			

CRF Report for Study E6270229



Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Week 12(2)

Blank? Y

CRF Page #: 16

Visit: WEEK 12

Visit Date: 00-00-

Document #: R169069213

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

Section: Proventil_Admin	5 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:35	
	Last Modification Time:		
	Page number: 38		
PROVENTIL ADMINISTRATION			
Actual Time			
of Proventil			
Date	Administration	Amount Administered	Comments

Section: Post_Bronch_Spir	6 of 11	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:35	
		Last Modification Time:	
		Page number: 38	
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT			
	Actual Time of FEV1/FVC	Testing Position	
Date	Test	FEV1 L	FEV1 Predicted (%)
		FVC L	FVC Predicted (%)
			Comments

Section: Used Study Tobac		7 of 11		Blank? Y		Section Status: Created			
Visit: WEEK 12				Section Date: 00-00-					
Entered By: Christina Breedlove				Entry Time: 06-12-2007 15:22:35					
				Last Modification Time:					
				Page number: 39					
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION									
				Number of Study Tobacco-Heating		Weight of			
Scheduled Collection		Stop		Stop		Cigarettes Collected		Any Product	
Timepoint		Start Date		Start Time		(a)		Deviation?	
								If yes, # of other	
								Brand	
								Comments	

Section:	Used_Study_Snus	8 of 11	Blank?	Y	Section Status:	Created
Visit:	WEEK 12		Section Date:	00-00-		
Entered By:	Christina Breedlove		Entry Time:	06-12-2007 15:22:35		

CRF Report for Study E6270229



Patient: 3022
CRF: Week 12(2)
Visit: WEEK 12

Site: CDB_001
Blank? Y
Visit Date: 00-00-

Investigator: CDB_001
CRF Page #: 16
Document #: R169069213

Section: Used_Study_Snus 8 of 11

Last Modification Time:
Page number: 40

USED STUDY SNUS COLLECTION

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

Section: Used_Study_Burn 9 of 11 Blank? Y Section Status: Created
Visit: WEEK 12 Section Date: 00-00-
Entered By: Christina Breedlove Entry Time: 06-12-2007 15:22:35
Last Modification Time:
Page number: 41

USED STUDY TOBACCO-BURNING CIGARETTE COLLECTION

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

Section: Used_Butt_Measur 10 of 11 Blank? Y Section Status: Created
Visit: WEEK 12 Section Date: 00-00-
Entered By: Christina Breedlove Entry Time: 06-12-2007 15:22:35
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: 00-00-
Entered By: Christina Breedlove Entry Time: 06-12-2007 15:22:35
Last Modification Time:
Page number: 43

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

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



Patient: 3022

CRF: Week 12(3)

Visit: WEEK 12

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 15:22:40

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 17

Document #: R169069313

CRF Status: Created

Approver:

Verifier:

Section: Unused_Study_Pro	1 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:40	
		Last Modification Time:	
		Page number: 44	
Unused Study Product Returned			
Date	Actual Time	Product Returned	Flavor
			Amount Returned
			Packs Individual Cigarettes / pouches

Section: Study_Prod_Dispe	2 of 2	Blank? Y	Section Status: Created
Visit: WEEK 12		Section Date: 00-00-	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:22:40	
		Last Modification Time:	
		Page number: 44	
STUDY PRODUCT DISPENSATION			
Date	Actual Time	Product Dispensed	Flavor
			Amount Dispensed

CRF Report for Study E6270229



Patient: 3022

CRF: Week 14

Visit: WEEK 14

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:13

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 18

Document #: R169313913

CRF Status: Created

Approver:

Verifier:

Section: HDyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:13	
		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: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:13	
		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: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:13	
		Last Modification Time:	
		Page number: 45	
VITAL SIGNS			
	Blood Pressure		Oral
Actual Time	Systolic	Diastolic	Pulse
			Respiratory Rate
			Temperature
			xxx.x
Unit			
Comments			

Section: Unused_Study_Pro	4 of 5	Blank? Y	Section Status: Created
Visit: WEEK 14		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:13	
		Last Modification Time:	

CRF Report for Study E6270229

6

Patient: 3022

CRF: Week 14

Visit: WEEK 14

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 18

Document #: R169313913

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: 10-12-2007

Entered By: Christina Breedlove

Entry Time: 10-12-2007 17:22:13

Last Modification Time:

Page number: 46

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229



Patient: 3022

CRF: Week 16

Visit: WEEK 16

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:26

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 19

Document #: R169314213

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:26	
		Last Modification Time:	
		Page number: 47	
<p>PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p> <p style="text-align: right;">YES / NO</p>			

Section: Hdyf_Oral_Health	2 of 6	Blank? Y	Section Status: Created												
Visit: WEEK 16		Section Date: 10-12-2007													
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:26													
		Last Modification Time:													
		Page number: 47													
<p>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 30%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;">Oral Health</td> <td style="width: 50%;"></td> </tr> <tr> <td></td> <td></td> <td>Questions</td> <td></td> </tr> <tr> <td>Actual Time</td> <td>HDYF Performed?</td> <td>Performed?</td> <td>Comments</td> </tr> </table>						Oral Health				Questions		Actual Time	HDYF Performed?	Performed?	Comments
		Oral Health													
		Questions													
Actual Time	HDYF Performed?	Performed?	Comments												

Section: Vital	3 of 6	Blank? Y	Section Status: Created																												
Visit: WEEK 16		Section Date: 10-12-2007																													
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:26																													
		Last Modification Time:																													
		Page number: 47																													
<p>VITAL SIGNS</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;">Blood Pressure</td> <td style="width: 15%;"></td> <td style="width: 15%;">Oral</td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>Actual Time</td> <td>Systolic</td> <td>Diastolic</td> <td>Pulse</td> <td>Respiratory Rate</td> <td>Temperature</td> <td>Unit</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td>xxx.x</td> <td></td> </tr> <tr> <td colspan="7">Comments</td> </tr> </table>					Blood Pressure		Oral				Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit						xxx.x		Comments						
	Blood Pressure		Oral																												
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Temperature	Unit																									
					xxx.x																										
Comments																															

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16		Section Date: 10-12-2007	

CRF Report for Study E6270229



Patient: 3022
CRF: Week 16
Visit: WEEK 16

Site: CDB_001
Blank? Y
Visit Date: 10-12-2007

Investigator: CDB_001
CRF Page #: 19
Document #: R169314213

Section: Expired_Carbon_M	4 of 6		
Entered By: Christina Breedlove	Entry Time: 10-12-2007 17:22:26		
Last Modification Time:			
Page number: 47			
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Unused_Study_Pro	5 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16	Section Date: 10-12-2007		
Entered By: Christina Breedlove	Entry Time: 10-12-2007 17:22:26		
Last Modification Time:			
Page number: 48			
Unused Study Product Returned			
Product Returned	Flavor	Amount Returned	
		Packs	Individual Cigarettes / pouches

Section: Study_Prod_Dispe	6 of 6	Blank? Y	Section Status: Created
Visit: WEEK 16	Section Date: 10-12-2007		
Entered By: Christina Breedlove	Entry Time: 10-12-2007 17:22:26		
Last Modification Time:			
Page number: 48			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRF Report for Study E6270229

Patient: 3022

CRF: Week 18

Visit: WEEK 18

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:35

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 20

Document #: R169314413

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:35	
		Last Modification Time:	
		Page number: 49	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
		Oral Health Questions	
Actual Time	HDYF Performed?	Performed?	Comments

Section: Expired_Carbon_M	2 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:35	
		Last Modification Time:	
		Page number: 49	
EXPIRED CARBON MONOXIDE			
Actual Time	ECO Level (ppm)	%COHb	Comments

Section: Vital	3 of 5	Blank? Y	Section Status: Created
Visit: WEEK 18		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:35	
		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: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:35	
		Last Modification Time:	

CRF Report for Study E6270229



Patient: 3022
CRF: Week 18
Visit: WEEK 18

Site: CDB_001
Blank? Y
Visit Date: 10-12-2007

Investigator: CDB_001
CRF Page #: 20
Document #: R169314413

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: 10-12-2007		
Entered By: Christina Breedlove	Entry Time: 10-12-2007 17:22:35		
Last Modification Time:			
Page number: 50			
STUDY PRODUCT DISPENSATION			
Actual Time	Product Dispensed	Flavor	Amount Dispensed

CRF Report for Study E6270229



Patient: 3022

CRF: Week 20

Visit: WEEK 20

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:44

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 21

Document #: R169314613

CRF Status: Created

Approver:

Verifier:

Section: Pro_Questionnaire	1 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:44	
		Last Modification Time:	
		Page number: 51	
<p>PRO QUESTIONNAIRES</p> <p>With the possible exception of urinating, did subject complete Smoker Core Questionnaire PRIOR to any study procedures being performed?</p>			YES / NO

Section: Hdyl_Oral_Health	2 of 6	Blank? Y	Section Status: Created								
Visit: WEEK 20		Section Date: 10-12-2007									
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:44									
		Last Modification Time:									
		Page number: 51									
<p>HDYF? / ORAL HEALTH QUESTIONS INQUIRY</p> <table style="width: 100%; border: none;"> <tr> <td></td> <td style="text-align: center;">Oral Health Questions</td> </tr> <tr> <td style="text-align: center;">Actual Time</td> <td style="text-align: center;">HDYF Performed?</td> </tr> <tr> <td></td> <td style="text-align: center;">Performed?</td> </tr> <tr> <td></td> <td style="text-align: center;">Comments</td> </tr> </table>					Oral Health Questions	Actual Time	HDYF Performed?		Performed?		Comments
	Oral Health Questions										
Actual Time	HDYF Performed?										
	Performed?										
	Comments										

Section: Vital	3 of 6	Blank? Y	Section Status: Created																								
Visit: WEEK 20		Section Date: 10-12-2007																									
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:44																									
		Last Modification Time:																									
		Page number: 51																									
<p>VITAL SIGNS</p> <table style="width: 100%; border: none;"> <tr> <td></td> <td colspan="2" style="text-align: center;">Blood Pressure</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">Actual Time</td> <td style="text-align: center;">Systolic</td> <td style="text-align: center;">Diastolic</td> <td style="text-align: center;">Pulse</td> <td style="text-align: center;">Respiratory Rate</td> <td style="text-align: center;">Oral Temperature xxx.x</td> <td style="text-align: center;">Unit</td> <td></td> </tr> <tr> <td colspan="8" style="border: none;"> <div style="border: 1px solid black; height: 20px; width: 100%;"></div> </td> </tr> </table>					Blood Pressure							Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature xxx.x	Unit		<div style="border: 1px solid black; height: 20px; width: 100%;"></div>							
	Blood Pressure																										
Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature xxx.x	Unit																					
<div style="border: 1px solid black; height: 20px; width: 100%;"></div>																											

Section: Expired_Carbon_M	4 of 6	Blank? Y	Section Status: Created
Visit: WEEK 20		Section Date: 10-12-2007	

CRF Report for Study E6270225



Patient: 3022

CRF: Week 20

Visit: WEEK 20

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 21

Document #: R169314613

Section: Expired_Carbon_M 4 of 6

Entered By: Christina Breedlove

Entry Time: 10-12-2007 17:22:44

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: 10-12-2007

Entered By: Christina Breedlove

Entry Time: 10-12-2007 17:22:44

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: 10-12-2007

Entered By: Christina Breedlove

Entry Time: 10-12-2007 17:22:44

Last Modification Time:

Page number: 52

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270229



Patient: 3022

CRF: Week 22

Visit: WEEK 22

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Entry Time: 10-12-2007 17:22:53

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 22

Document #: R169314813

CRF Status: Created

Approver:

Verifier:

Section: Hdyf_Oral_Health	1 of 5	Blank? Y	Section Status: Created
Visit: WEEK 22		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:53	
		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: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:53	
		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: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:53	
		Last Modification Time:	
		Page number: 53	
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 22		Section Date: 10-12-2007	
Entered By: Christina Breedlove		Entry Time: 10-12-2007 17:22:53	
		Last Modification Time:	

CRF Report for Study E6270229

Patient: 3022

CRF: Week 22

Visit: WEEK 22

Site: CDB_001

Blank? Y

Visit Date: 10-12-2007

Investigator: CDB_001

CRF Page #: 22

Document #: R169314813

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: 10-12-2007

Entered By: Christina Breedlove

Entry Time: 10-12-2007 17:22:53

Last Modification Time:

Page number: 54

STUDY PRODUCT DISPENSATION

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

CRF Report for Study E6270225

Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Week 24 (Eos)

Blank? N

CRF Page #: 23

Visit: WEEK 24 (EOS)

Visit Date: 12-10-2007

Document #: R169071213

Entered By: Christina Breedlove

Entry Time: 06-12-2007 15:36:37

CRF Status: Entry Complete

Discrepancies: Closed

Modification Time: 10-12-2007 16:45:55

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Pro_Questionnaire	1 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:36:37	
		Last Modification Time: 06-12-2007 15:37:51	
		Page number: 55	

Date	PRO QUESTIONNAIRES	YES / NO
12-10-2007	1. With the possible exception of urinating, did subject complete Smoker Routine Questionnaire PRIOR to any study procedures being performed?	YES

Section: Urine_Drug	2 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:36:37	
		Last Modification Time: 06-12-2007 15:37:51	
		Page number: 55	

Date	Drug Screen	Drug Screen Result
12-10-2007		NEG

Section: Alcohol_Screen	3 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:36:37	
		Last Modification Time: 06-12-2007 15:37:51	
		Page number: 55	

Date	Alcohol Screen	Breathalyzer Result
12-10-2007		NEG

Section: Preg_Test	4 of 12	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:36:37	
		Last Modification Time: 06-12-2007 15:37:51	
		Page number: 55	

CRF Report for Study E6270229

Patient: 3022

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Investigator: CDB_001

CRF Page #: 23

Document #: R169071213

Section: Preg_Test

4 of 12

Pregnancy Test

Date	Result
12-10-2007	N/A, MALE OR FEMA LE

Section: Urine_Coll

5 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 12-10-2007

Entered By: Christina Breedlove

Entry Time: 06-12-2007 15:36:37

Last Modification Time: 10-12-2007 16:45:55

Page number: 55

24-Hour Urine Collection

Scheduled Timepoint	Start Date	Start Time	Stop Date	Stop Time	Total Volume	Comments
SPOT URINE VOID	12-10-2007	1001	NA	NA	NA	
0 HOUR TO 24 HOURS	ND	ND	ND	ND	ND	

Section: ECG

6 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 12-10-2007

Entered By: Christina Breedlove

Entry Time: 06-12-2007 15:36:37

Last Modification Time: 06-12-2007 15:40:02

Page number: 56

12-LEAD ELECTROCARDIOGRAM REPORT

Actual Time	Ventricular Heart Rate
0938	47

Cardiac Cycle Measurements

PR Interval	QRS Duration	QT Interval	QTc Interval
148	94	480	442

ECG INTERPRETATION:

NORMAL

Comments (related to abnormal, CS findings only):

Section: Hdyf_Oral_Health

7 of 12

Blank? N

Section Status: Entry Complete

Visit: WEEK 24 (EOS)

Section Date: 12-10-2007

Entered By: Christina Breedlove

Entry Time: 06-12-2007 15:36:37

Last Modification Time: 09-12-2007 12:24:01

Page number: 57

CRF Report for Study E6270229



Patient: 3022
CRF: Week 24 (Eos)
Visit: WEEK 24 (EOS)

Site: CDB_001
Blank? N
Visit Date: 12-10-2007

Investigator: CDB_001
CRF Page #: 23
Document #: R169071213

Section: Hdyf_Oral_Health		7 of 12	
HDYF? / ORAL HEALTH QUESTIONS INQUIRY			
Date	Actual Time	HDYF Performed?	Oral Health Questions Performed? Comments
12-10-2007	NR	YES	YES

Section: Vital		8 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007		Entry Time: 06-12-2007 15:36:37		Last Modification Time: 06-12-2007 15:42:20	
Entered By: Christina Breedlove		Page number: 57					
VITAL SIGNS							
Blood Pressure							
Date	Actual Time	Systolic	Diastolic	Pulse	Respiratory Rate	Oral Temperature	Unit
12-10-2007	0928	125	078	046	12	36.6	C
						xxx.x	
Comments							

Section: Oral_Health_Exam		9 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007		Entry Time: 06-12-2007 15:36:37		Last Modification Time: 09-12-2007 12:24:22	
Entered By: Christina Breedlove		Page number: 57					
ORAL HEALTH EXAMINATION							
Date	Procedure			Relevant Findings?*		Findings	
12-10-2007	ORAL HEALTH QUESTIONS PERFORMED			NO			
	EVIDENCE OF LEUKOPLAKIA			NO			
	OTHER ORAL KERATOSIS			NO			

Section: Phys_Exam		10 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007		Entry Time: 06-12-2007 15:36:37		Last Modification Time: 06-12-2007 15:43:41	
Entered By: Christina Breedlove		Page number: 58					
PHYSICAL EXAMINATION							
Date							

CRF Report for Study E6270229

Patient: 3022

CRF: Week 24 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Investigator: CDB_001

CRF Page #: 23

Document #: R169071213

Section: Phys_Exam		10 of 12	
12-10-2007			
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	NE	

Section: Weight_Height		11 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007		Entry Time: 06-12-2007 15:36:37			
Entered By: Christina Breedlove		Last Modification Time: 06-12-2007 15:44:55		Page number: 58			
WEIGHT & HEIGHT							
Date	Weight	Unit	Height	Unit			
12-10-2007	106.2	KG	ND				
	xxx.x		xxx.x				

Section: Lab_Eval		12 of 12		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007		Entry Time: 06-12-2007 15:36:37			
Entered By: Christina Breedlove		Last Modification Time: 06-12-2007 15:47:18		Page number: 59			
Laboratory Evaluations							
Date							
12-10-2007							
Were the scheduled laboratory samples obtained?				YES	No, specify		
Requisition Number 1		Q514909					
Requisition Number 2 (if applicable)							
Were there any clinically significant labs?				NO	(Yes, specify below)		
Requisition Number	Test Name	H/L	Lab ID	Lab Name			

CRF Report for Study E6270229

Patient: 3022

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Entered By: Christina Breedlove

Discrepancies: Active

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Entry Time: 06-12-2007 15:49:54

Modification Time: 10-12-2007 09:44:40

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 24

Document #: R169072813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pk_Blood_Biomark	1 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:49:54	
		Last Modification Time: 09-12-2007 12:27:50	
		Page number: 59	
Blood Sampling For Biomarkers/Chemistry/Hematology (following an overnight fast)			
Date	Actual Time	Comments	
12-10-2007	1006		

Section: Expired_Carbon_M	2 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:49:54	
		Last Modification Time: 09-12-2007 12:25:56	
		Page number: 59	
EXPIRED CARBON MONOXIDE			
Date	Actual Time	ECO Level (ppm)	%COHb
12-10-2007	0943	0	00.0
Comments			

Section: Blood_Sampl_Cohb	3 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:49:54	
		Last Modification Time: 09-12-2007 12:28:11	
		Page number: 59	
Blood Sampling for %COHb			
Date	Actual Time	Comments	
12-10-2007	ND	PER SPONSOR REQUEST	

Section: Pre_Bronch_Spir	4 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:49:54	
		Last Modification Time: 06-12-2007 16:04:50	
		Page number: 60	

CRF Report for Study E6270229

Patient: 3022

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Investigator: CDB_001

CRF Page #: 24

Document #: R169072813

Section: Pre_Bronch_Spir		4 of 11					
PRE-BRONCHODILATOR BEST BASELINE SPIROMETRY TEST RESULT							
Actual Time of FEV1/FVC		Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						
12-10-2007	0951	STANDI NG	3.64	88	4.54	83	

Section: Proventil_Admin	5 of 11	Blank? N	Section Status: Entry Complete
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007	
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:49:54	
		Last Modification Time: 09-12-2007 12:31:58	
		Page number: 60	
PROVENTIL ADMINISTRATION			
Actual Time			
of Proventil			
Date	Administration	Amount Administered	Comments
12-10-2007	ND	NA	

Section: Post_Bronch_Spir	6 of 11	Blank? N	Section Status: Entry Complete				
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007					
Entered By: Christina Breedlove		Entry Time: 06-12-2007 15:49:54					
		Last Modification Time: 09-12-2007 12:41:27					
		Page number: 60					
POST-BRONCHODILATOR BEST SPIROMETRY TEST RESULT							
	Actual Time of FEV1/FVC	Testing Position	FEV1 L	FEV1 Predicted (%)	FVC L	FVC Predicted (%)	Comments
Date	Test						
12-10-2007	ND	NA	ND	ND	ND	ND	

Section: Used_Study_Tobac	7 of 11	Blank? Y	Section Status: Created			
Visit: WEEK 24 (EOS)	Section Date: 12-10-2007					
Entered By: Christina Breedlove	Entry Time: 06-12-2007 15:49:54					
Last Modification Time:						
Page number: 61						
USED STUDY TOBACCO-HEATING CIGARETTE COLLECTION						
			Number of Study Tobacco-Heating Cigarettes	Weight of Cigarettes Collected	Any Product	If yes, # of other
Scheduled Collection	Stop	Stop	Cigarettes	Cigarettes Collected		

CRF Report for Study E6270229

Patient: 3022

CRF: Week 24-2 (Eos)

Visit: WEEK 24 (EOS)

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Investigator: CDB_001

CRF Page #: 24

Document #: R169072813

Section: Used_Study_Tobac	7 of 11								
Timepoint	Start Date	Start Time	Date	Time	Collected	(g)	Deviation?	Brand	Comments

Section: Used_Study_Snus	8 of 11	Blank? N	Section Date: 12-10-2007	Entry Time: 06-12-2007 15:49:54	Last Modification Time: 09-12-2007 12:30:49	Page number: 62	Section Status: Entry Complete
Visit: WEEK 24 (EOS)							
Entered By: Christina Breedlove							

USED STUDY SNUS COLLECTION								
Scheduled Collection	Timepoint	Start Date	Start Time	Stop Date	Stop Time	Number of Study Pouches Collected	Any Product Deviation?	If Yes, # of other brand: Comments
	24 HOURS PRIOR TO CHECK-IN	ND	ND	ND	ND	ND	NA	
	24 HOURS IN-HOUSE	ND	ND	ND	ND	ND	NA	

Section: Used_Study_Burn	9 of 11	Blank? Y	Section Date: 12-10-2007	Entry Time: 06-12-2007 15:49:54	Last Modification Time:	Page number: 63	Section Status: Created
Visit: WEEK 24 (EOS)							
Entered By: Christina Breedlove							

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 Date: 12-10-2007	Entry Time: 06-12-2007 15:49:54	Last Modification Time:	Page number: 64	Section Status: Created
Visit: WEEK 24 (EOS)							
Entered By: Christina Breedlove							

USUAL STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT				
Scheduled Collection				
Date	Period	Cigarette Butt Number	Cigarette Butt Measurement (mm)	

Section: Used_Butt_Measur	11 of 11	Blank? Y	Section Date: 12-10-2007	Entry Time: 06-12-2007 15:49:54	Last Modification Time:	Section Status: Created
Visit: WEEK 24 (EOS)						
Entered By: Christina Breedlove						

CRF Report for Study E6270229

Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Week 24-2 (Eos)

Blank? N

CRF Page #: 24

Visit: WEEK 24 (EOS)

Visit Date: 12-10-2007

Document #: R169072813

Section: Used_Butt_Measur 11 of 11

Page number: 65

USED STUDY TOBACCO-BURNING CIGARETTE BUTT MEASUREMENT

Scheduled Collection

Date

Period

Cigarette Butt Number

Cigarette Butt Measurement (mm)

CRF Report for Study E6270229

Patient: 3022

CRF: Week 24-3

Visit: WEEK 24 (EOS)

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Entry Time: 06-12-2007 16:04:51

Modification Time: 06-12-2007 16:05:46

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 25

Document #: R169073713

CRF Status: Entry Complete

Approver:

Verifier:

Section: Unused_Study_Pro		Blank? N		Section Status: Entry Complete	
Visit: WEEK 24 (EOS)		Section Date: 12-10-2007			
Entered By: Christina Breedlove		Entry Time: 06-12-2007 16:04:51			
		Last Modification Time: 06-12-2007 16:05:46			
		Page number: 65A			
Unused Study Product Returned					
				Amount Returned	
Date	Actual Time	Product Returned	Flavor	Packs	Individual Cigarettes / pouches
12-10-2007	BLANK	SNUS	FROST	0	0

CRF Report for Study E6270229



Patient: 3022

CRF: Precon_Med

Visit: PRECON_MEDS

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Entry Time: 06-12-2007 16:05:47

Modification Time: 09-12-2007 12:32:43

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 26

Document #: R169073813

CRF Status: Entry Complete

Approver:

Verifier:

Section: Pre_Conmed

Blank? N

Section Status: Entry Complete

Visit: PRECON_MEDS

Section Date: 12-10-2007

Entered By: Christina Breedlove

Entry Time: 06-12-2007 16:05:47

Last Modification Time: 09-12-2007 12:32:43

Page number: 66

Previous and Concomitant Medications

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

NO

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

CRF Report for Study E6270229



Patient: 3022

CRF: AE

Visit: AE

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 00-00-

Entry Time: 06-12-2007 16:06:28

Modification Time: 09-12-2007 12:33:01

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 27

Document #: R169073913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Ae_Med

Blank? N

Section Status: Entry Complete

Visit: AE

Section Date: 00-00-

Entered By: Christina Breedlove

Entry Time: 06-12-2007 16:06:28

Last Modification Time: 09-12-2007 12:33:01

Page number: 67

Adverse Events

Did the subject experience any adverse events?

NO

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

CRF Report for Study E6270229



Patient: 3022

CRF: Ecg_Unscheduled

Visit: ECG_UNSCHE

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 16:06:36

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 28

Document #: R169074013

CRF Status: Created

Approver:

Verifier:

Section: ECG

Blank? Y

Section Status: Created

Visit: ECG_UNSCHE

Section Date: 00-00-

Entered By: Christina Breedlove

Entry Time: 06-12-2007 16:06:36

Last Modification Time:

Page number: 68

UNSCHEDULED 12-LEAD ELECTROCARDIOGRAM REPORT

Ventricular

Cardiac Cycle Measurements

Date	Actual Time	Heart Rate	PR Interval	QRS Duration	QT Interval	QTc Interval	Interpretation	Comments
------	-------------	------------	-------------	--------------	-------------	--------------	----------------	----------

CRF Report for Study E6270229



Patient: 3022

CRF: Lab_Unscheduled

Visit: LAB_UNSCHEd

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 01-06-2007

Entry Time: 06-12-2007 13:31:58

Modification Time: 10-12-2007 09:44:40

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 29

Document #: R169056913

CRF Status: Entry Complete

Approver:

Verifier:

Section: Lab_Eval

Blank? N

Section Status: Entry Complete

Visit: LAB_UNSCHEd

Section Date: 01-06-2007

Entered By: Christina Breedlove

Entry Time: 06-12-2007 13:31:58

Last Modification Time: 09-12-2007 12:36:44

Page number: 69

Unscheduled Laboratory Evaluations

Clinically
Significant?
NO

Test Name

High(H)/Low(L)

If Clinically Significant, Specify

Lab ID

Lab Name

Comments

Date
01-06-2007

Requisition Number
P177579

CRF Report for Study E6270229



Patient: 3022

CRF: Vital_Unscheduled

Visit: VITAL_UNSCHEDED

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 16:06:42

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 30

Document #: R169074113

CRF Status: Created

Approver:

Verifier:

Section: Vital

Blank? Y

Section Status: Created

Visit: VITAL_UNSCHEDED

Section Date: 00-00-

Entered By: Christina Breedlove

Entry Time: 06-12-2007 16:06:42

Last Modification Time:

Page number: 70

UNSCHEDULED VITAL SIGNS

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

CRF Report for Study E6270229



Patient: 3022

Site: CDB_001

Investigator: CDB_001

CRF: Stdy_Prdt_Dis_Unschedule

Blank? Y

CRF Page #: 31

Visit: STDY_PRDT_UNSCHE

Visit Date: 00-00-

Document #: R169074213

Entered By: Christina Breedlove

Entry Time: 06-12-2007 16:06:47

CRF Status: Created

Discrepancies: None

Modification Time:

Approval Status: Not Approved

Approval Time:

Approver:

Verification: Not Verified

Verification Time:

Verifier:

Comment:

Section: Study_Prod_Dispe	Blank? Y	Section Status: Created
Visit: STDY_PRDT_UNSCHE	Section Date: 00-00-	
Entered By: Christina Breedlove	Entry Time: 06-12-2007 16:06:47	
	Last Modification Time:	
	Page number: 71	

UNSCHEDULED STUDY PRODUCT DISPENSATION					
Date	Actual Time	Product Dispensed	Flavor	Amount Dispensed	Comments

CRF Report for Study E6270229



Patient: 3022

CRF: Expired_Co2_Unscheduled

Visit: EXPIRED_CO2_UNSC

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 16:07:13

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 32

Document #: R169074313

CRF Status: Created

Approver:

Verifier:

Section: Expired_Carbon_M

Blank? Y

Section Status: Created

Visit: EXPIRED_CO2_UNSC

Section Date: 00-00-

Entered By: Christina Breedlove

Entry Time: 06-12-2007 16:07:13

Last Modification Time:

Page number: 72

UNSCHEDULED EXPIRED CARBON MONOXIDE

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

CRF Report for Study E6270229



Patient: 3022

CRF: Oral_Health_Unscheduled

Visit: ORAL_HEALTH_UNSC

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 16:10:02

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 33

Document #: R169074413

CRF Status: Created

Approver:

Verifier:

Section: Oral_Health_Exam	Blank? Y	Section Status: Created
Visit: ORAL_HEALTH_UNSC	Section Date: 00-00-	
Entered By: Christina Breedlove	Entry Time: 06-12-2007 16:10:02	
	Last Modification Time:	
	Page number: 73	

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

CRF Report for Study E6270229



Patient: 3022

CRF: Spirometry_Unscheduled

Visit: SPIRO_TEST_UNSCH

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? Y

Visit Date: 00-00-

Entry Time: 06-12-2007 16:10:08

Modification Time:

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 34

Document #: R169074513

CRF Status: Created

Approver:

Verifier:

Section: Pre_Bronch_Spir		Blank? Y		Section Status: Created	
Visit: SPIRO_TEST_UNSCH		Section Date: 00-00-			
Entered By: Christina Breedlove		Entry Time: 06-12-2007 16:10:08			
		Last Modification Time:			
		Page number: 74			
UNSCHEDULED SPIROMETRY TEST RESULT					
	Actual Time of FEV1/FVC	Testing Position	Timepoint based on Proventil Administration	Proventil Administration (and time of Administration)	(Time)
Date	Test			FEV1 L	FEV1 Predicted (%)
					FVC L
					FVC Predicted (%)
					Comments

CRF Report for Study E6270229

Patient: 3022

CRF: Study_Completion

Visit: STUDY_COMP

Entered By: Christina Breedlove

Discrepancies: None

Approval Status: Not Approved

Verification: Not Verified

Comment:

Site: CDB_001

Blank? N

Visit Date: 12-10-2007

Entry Time: 06-12-2007 16:10:14

Modification Time: 06-12-2007 16:10:56

Approval Time:

Verification Time:

Investigator: CDB_001

CRF Page #: 35

Document #: R169074613

CRF Status: Entry Complete

Approver:

Verifier:

Section: Study_Comp

Blank? N

Section Status: Entry Complete

Visit: STUDY_COMP

Section Date: 12-10-2007

Entered By: Christina Breedlove

Entry Time: 06-12-2007 16:10:14

Last Modification Time: 06-12-2007 16:10:56

Page number: 75

Study Completion

Did the subject complete the study?

NO

Date the subject completed OR withdraw from the study:

12-10-2007

Reason for Withdrawal

CONSENT

Specify

Investigator Comments

Principal Investigator

Date

17 DEC 2007

Covance CLS

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

ACCESSION NO. N702585

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: 09:54 DATE: 11-May-2007

DATE RECEIVED IN LABORATORY: 12-May-2007

DATE REPORTED BY LABORATORY: 14-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B SURFACE ANTIGEN

HBSAG

Negative

No Ref Rng

HEPATITIS C VIRUS ANTIBODY

ANTI-HCV

Negative

No Ref Rng

HEPATITIS B SURFACE ANTIBODY

HBSAB

Negative

No Ref Rng

Handwritten signature
15 MAY 2007

Handwritten signature
Investigator Signature:

Handwritten date
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

Handwritten text
OCD JB 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. N702585

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: 09:54 DATE: 11-May-2007

DATE RECEIVED IN LABORATORY: 12-May-2007

DATE REPORTED BY LABORATORY: 12-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

SCREEN CHEMISTRY PANEL

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	78		35-131 U/L
ALT (SGPT)	47	H	6-43 U/L
AST (SGOT)	17		11-36 U/L
GGT	49		10-61 U/L
LDH	116		53-234 U/L
Urea Nitr	17		4-24 mg/dL
Creatinine	0.7		0.5-1.3 mg/dL
Glucose	127	H	70-115 mg/dL
Uric Acid	4.4		2.5-8.3 mg/dL
Calcium	9.6		8.3-10.6 mg/dL
Phosphorus	3.4		2.2-5.1 mg/dL
Total Prot	7.1		6.1-8.4 g/dL
Albumin	3.9		3.3-4.9 g/dL
Sodium	143		132-147 mEq/L
Potassium	4.3		3.4-5.4 mEq/L
Chloride	106		94-112 mEq/L
Triglycer	143		58-320 mg/dL
Cholest	233		170-291 mg/dL

[]

[]

[]

[]

14 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

QC'd 22 May 2007 (INV) JS

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. N702585

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: 09:54 DATE: 11-May-2007

DATE RECEIVED IN LABORATORY: 12-May-2007

DATE REPORTED BY LABORATORY: 12-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY & DIFFERENTIAL PANEL

HGB	15.0	12.7-18.1 g/dL
HCT	46	39-54 %
RBC	4.5	4.5-6.4 x10 ⁶ /uL
MCV	102 H	79-96 fL
MCH	33	26-34 pg
MCHC	33	31-38 g/dL
RDW	13.2	12.0-15.0 %
RBC Morph	Macrocytic	
WBC	7.56	3.80-10.70 x10 ³ /uL
Neutrophil	4.51	1.96-7.23 x10 ³ /uL
Lymphocyte	2.47	0.91-4.28 x10 ³ /uL
Monocytes	0.45	0.12-0.92 x10 ³ /uL
Eosinophil	0.10	0.00-0.57 x10 ³ /uL
Basophils	0.04	0.00-0.20 x10 ³ /uL
Neutrophil	59.6	40.5-75.0 %
Lymphocyte	32.6	15.4-48.5 %
Monocytes	5.9	2.6-10.1 %
Eosinophil	1.3	0.0-6.8 %
Basophils	0.5	0.0-2.0 %
Platelets	193	140-400 x10 ³ /uL

[]

[]

14 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

QC'd 13 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. N702585

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: 09:54 DATE: 11-May-2007

DATE RECEIVED IN LABORATORY: 12-May-2007

DATE REPORTED BY LABORATORY: 12-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

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 1.028

1.003-1.035

pH 5.5

5.0-8.0

Protein Negative

Ref Rng: Negative

Glucose Normal

Ref Rng: Normal

Ketones Negative

Ref Rng: Negative

Bilirubin Negative

Ref Rng: Negative

Urobilin Normal

Ref Rng: Normal

Blood Negative

Ref Rng: Negative

Nitrite Negative

Ref Rng: Negative

Leuk Est Negative

Ref Rng: Negative

Microscop Positive

CELLULAR ELEMENTS

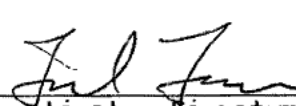
WBC 3

0-5 /HPF

MISCELLANEOUS ELEMENTS

Mucous Present

Ref Rng: Not present


Investigator Signature:

14 MAY 2007
Date:

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B17177

QC'd JB 22 MAY 2007 (INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. N702585

Page 1 of 1

INVESTIGATOR: (B17177)

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Daytona Beach, FL 32117

SPONSOR REPORT TO:

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

Screen

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DATE REPORTED BY LABORATORY: 12-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 109 45-160 ug/dL

HEPATITIS A ANTIBODY-IGM

HepA IgMab Negative No Ref Rng

14 MAY 2007

Frank Farmer
Investigator Signature:

14 MAY 2007
Date:

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B17177

QC'd JB 22 MAY 2007 (INV)

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SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HIV 1/HIV 2 ANTIBODY SCREEN

HIV-1/2

Non-Reactive

Reference Range:

Non-Reactive

14 MAY 2007

Frank Farmer
Investigator Signature:

14 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 JB (INV) *14 MAY 2007*

Covance CLS

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INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 1

SPONSOR REPORT TO:

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DATE REPORTED BY LABORATORY: 12-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEPATITIS B CORE ANTIBODY-IGM

Hep Bc IgM Negative Ref Rng: Negative

14 May 2007

Frank Farmer
Investigator Signature:

14 May 2007
Date:

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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
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LABORATORY REPORT

ACCESSION NO. N702585

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INVESTIGATOR NO.: 3

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VISIT: 1

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SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

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

14 May 2007

Frank Farmer
Investigator Signature:

14 May 2007
Date:

B17177

QC 14 May 2007 JLS (INV)

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. P205167

Page 1 of 1

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.

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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: R3022

PATIENT INITIALS: (b) (6)

VISIT: 24 HR UR

24 Hr Urine Collection

COLLECTION TIME: 15:50 DATE: 23-May-2007

DATE RECEIVED IN LABORATORY: 26-May-2007

DATE REPORTED BY LABORATORY: 26-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, 24 HR

U24h Creat 1931 H 800-1800 mg/24hr

UAlq24Crea 78.8 mg/dL No Ref Rng

[]

[]

ELAPSED DATE AND TIME, 24HR

Elpsd DST 1440 min

24 HR COLLECTION INFORMATION

Start Date 23-May-2007

Start Time 15:50

Stop Date 24-May-2007

Stop Time 15:50

TOTAL 24HR URINE VOLUME

Total Vol. 2450 mL

Handwritten signature
24 May 2007

Handwritten signature
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)

Handwritten: 07/30/07
Covance CLS

Covance CLS

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Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. P060627

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: R3022

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:26 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 15-Jun-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1

sICAM-1

282

115-306 ng/mL

18 Jun 2007

[Signature]
Investigator Signature:

18 Jun 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
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B20476

(INV)

*09/25/07
G. J. S.
S. J. S.*

Covance CLS

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LABORATORY REPORT

ACCESSION NO. P060627

Page 1 of 1

INVESTIGATOR: (B17177)

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c/o Melissa Zeis
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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: R3022

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:26 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

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SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

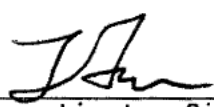
Yes

No

LIPID PANEL

Triglycer	180	58-320 mg/dL
Cholest	237	170-291 mg/dL
HDL Dex-S	41	28-71 mg/dL
LDL Chol	160	88-203 mg/dL

24 May 2007


Investigator Signature:

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B17177

(INV)

30 May 2007
Date:

Covance CLS

Marietta Henry, M.D., Director
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1900 Mason Ave
Daytona Beach, FL 32117

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

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3022

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

COLLECTION TIME: 06:26 DATE: 24-May-2007

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DATE REPORTED BY LABORATORY: 26-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HOMOCYSTEINE

*1 HCY 5.86 L 5.90-16.00 umol/L

[]

[✓]

29 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.

Farmer
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

(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. P060627

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c/o Melissa Zeis
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Daytona Beach, FL 32117

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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

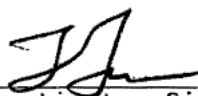
Is this Clinically
Significant/ Adverse
Event?

Yes

No

RBC CELL WASHING (4-ABP-HB)

Wash/Store Completed


Investigator Signature:

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B17177

(INV)

02 JUL 07
30mg 2007

30mg 2007
Date:

Covance CLS

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VISIT: 2

Week 0

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DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.4		0.2-1.2 mg/dL
Alk Phos	83		35-131 U/L
ALT (SGPT)	49	H	6-43 U/L
AST (SGOT)	20		11-36 U/L
GGT	51		10-61 U/L
LDH	129		53-234 U/L
Urea Nitr	10		4-24 mg/dL
Creatinine	0.7		0.5-1.3 mg/dL
Glucose	147	H	70-115 mg/dL
Uric Acid	3.8		2.5-8.3 mg/dL
Calcium	9.4		8.3-10.6 mg/dL
Phosphorus	3.6		2.2-5.1 mg/dL
Total Prot	6.9		6.1-8.4 g/dL
Albumin	3.7		3.3-4.9 g/dL
Sodium	140		132-147 mEq/L
Potassium	4.1		3.4-5.4 mEq/L
Chloride	103		94-112 mEq/L

*Repeat
Glucose
and UA
this week.*

29 May 2007

Investigator Signature:

Date:

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VISIT: 2

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SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	15.2	12.7-18.1 g/dL
HCT	48	39-54 %
RBC	4.7	4.5-6.4x10 ⁶ /uL
MCV	103 H	79-96 fL
MCH	33	26-34 pg
MCHC	32	31-38 g/dL
RDW	12.8	12.0-15.0 %
RBC Morph	Macrocytic	
WBC	8.28	3.80-10.70 x10 ³ /uL
Neutrophil	5.09	1.96-7.23 x10 ³ /uL
Lymphocyte	2.39	0.91-4.28 x10 ³ /uL
Monocytes	0.57	0.12-0.92 x10 ³ /uL
Eosinophil	0.19	0.00-0.57 x10 ³ /uL
Basophils	0.03	0.00-0.20 x10 ³ /uL
Neutrophil	61.5	40.5-75.0 %
Lymphocyte	28.9	15.4-48.5%
Monocytes	6.9	2.6-10.1 %
Eosinophil	2.3	0.0-6.8 %
Basophils	0.4	0.0-2.0 %
Platelets	205	140-400 x10 ³ /uL

[]

[/]

24 May 2007

Investigator Signature:

30 May 2007
Date:

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SCREENING NUMBER: S3084

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	1.024	1.003-1.035
pH	5.5	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	+4 H	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

[]

[]

Report UP
this week

MISCELLANEOUS ELEMENTS

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

29 May 2007

J. Farmer
Investigator Signature:

30 May 2007
Date:

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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

SPONSOR REPORT TO:

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Week 0

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DATE REPORTED BY LABORATORY: 25-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

TOTAL IRON

Total Iron 90 45-160 ug/dL

C-REACTIVE PROTEIN

CRP-HS 0.201 <=0.287 mg/dL

CARBOXYHEMOGLOBIN

Carboxyhem 6.8 % saturation
No Ref Rng

24 May 2007

J. L.
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

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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: 06:26 DATE: 24-May-2007

DATE RECEIVED IN LABORATORY: 25-May-2007

DATE REPORTED BY LABORATORY: 25-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

FIBRINOGEN

Fibrinogen

329

200-400 mg/dL

24 May 2007

J. 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

*Rec'd
09/Jul/07*

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. P060627

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:

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Medical Director
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3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

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VISIT: 2

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SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE CREATININE, SPOT

Rnd Ur Crt 126

mg/dL No Ref Rng

24 May 2007

[Signature]
Investigator Signature:

30 MAY 2007
Date:

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B17177

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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

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

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SEX: M BIRTHDATE: (b) (6)

AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

sICAM-1

sICAM-1

To follow

Handwritten: 24 May 2007

Handwritten Signature:
Investigator Signature:

Handwritten: 30 MAY 2007
Date:

H(High) or L(Low)=Values above or below Covance CLS reference range
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ACCESSION NO. P060627

Page 1 of 1

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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: 06:26 DATE: 24-May-2007

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DATE REPORTED BY LABORATORY: 25-May-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

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

Handwritten:
24 May 2007

Note #1 - No specimen received

Handwritten Signature
Investigator Signature:

Handwritten: 30 MAY 2007
Date:

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LABORATORY REPORT

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PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

Handwritten: 24 May 2007

Handwritten Signature: J. Farmer
Investigator Signature:

Handwritten: 30 May 2007
Date:

B17177

(INV)

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LABORATORY REPORT

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RANDOMIZATION NUMBER:

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VISIT: 2

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SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c 7.2

Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

Handwritten: 24 May 2007

Handwritten Signature:
Investigator Signature:

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B17177

(INV)

Handwritten: 30 May 2007

Handwritten: 30 May 2007
Date:

Covance CLS

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LABORATORY REPORT

ACCESSION NO. P060627

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Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER:

PATIENT INITIALS: (b) (6)

VISIT: 2

Week 0

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SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

OXIDIZED LDL

OxidizeLDL

To follow

P
24 May 2007

F. Farmer
Investigator Signature:

30 May 2007
Date:

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

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. P177579

Page 1 of 2

INVESTIGATOR: (B17177)

Frank Farmer, Jr., M.D.
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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: R3022

PATIENT INITIALS: (b) (6)

VISIT: 2

Retest

COLLECTION TIME: 10:59 DATE: 01-Jun-2007

DATE RECEIVED IN LABORATORY: 02-Jun-2007

DATE REPORTED BY LABORATORY: 02-Jun-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	82		35-131 U/L
ALT (SGPT)	57	H	6-43 U/L
AST (SGOT)	25		11-36 U/L
GGT	52		10-61 U/L
LDH	137		53-234 U/L
Urea Nitr	13		4-24 mg/dL
Creatinine	0.7		0.5-1.3 mg/dL
Glucose	131	H	70-115 mg/dL
Uric Acid	5.1		2.5-8.3 mg/dL
Calcium	9.5		8.3-10.6 mg/dL
Phosphorus	3.7		2.2-5.1 mg/dL
Total Prot	7.3		6.1-8.4 g/dL
Albumin	4.0		3.3-4.9 g/dL
Sodium	139		132-147 mEq/L
Potassium	4.3		3.4-5.4 mEq/L
Chloride	103		94-112 mEq/L

Handwritten notes:
Panic 6/2/07
fainting
6/2/07

[]	[]
[]	[]

Handwritten signature: Paul Farmer
Investigator Signature:

Handwritten date: 07 JUN 2007
Date:

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

B17177

(INV)

Covance CLS

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LABORATORY REPORT

ACCESSION NO. P177579

Page 2 of 2

INVESTIGATOR: (B17177)

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Daytona Beach, FL 32117

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3402 Kinsman Boulevard
Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3022

PATIENT INITIALS: (b) (6)

VISIT: 2

Retest

COLLECTION TIME: 10:59 DATE: 01-Jun-2007

DATE RECEIVED IN LABORATORY: 02-Jun-2007

DATE REPORTED BY LABORATORY: 02-Jun-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

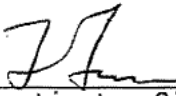
Color	Yellow	Ref Rng: Colorless or Yellow
Clarity	Clear	Ref Rng: Clear
Spec Grav	1.021	1.003-1.035
pH	5.5	5.0-8.0
Protein	Negative	Ref Rng: Negative
Glucose	Normal	Ref Rng: Normal
Ketones	Negative	Ref Rng: Negative
Bilirubin	Negative	Ref Rng: Negative
Urobilin	Normal	Ref Rng: Normal
Blood	Negative	Ref Rng: Negative
Nitrite	Negative	Ref Rng: Negative
Leuk Est	Negative	Ref Rng: Negative
Microscop	Positive	

CELLULAR ELEMENTS

WBC 1 0-5 /HPF

MISCELLANEOUS ELEMENTS

Mucous Present Ref Rng: Not present


Investigator Signature:

07 JUN 2007
Date:

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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. 0701297

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: R3022

PATIENT INITIALS: (b) (6)

VISIT: 4

Week 2

COLLECTION TIME: 11:35 DATE: 08-Jun-2007

DATE RECEIVED IN LABORATORY: 09-Jun-2007

DATE REPORTED BY LABORATORY: 09-Jun-2007

SEX: M BIRTHDATE: (b) (6) AGE: 55

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CARBOXYHEMOGLOBIN

Carboxyhem 1.5

% saturation

No Ref Rng

[Handwritten signature]
8 Jun 2007

[Handwritten signature]
Investigator Signature:

11/5/4/2007
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

Covance CLS

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

LABORATORY REPORT

ACCESSION NO. Q514909

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: R3022

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME: 10:06 DATE: 12-Oct-2007

DATE RECEIVED IN LABORATORY: 13-Oct-2007

DATE REPORTED BY LABORATORY: 15-Oct-2007

SEX: M BIRTHDATE: (b) (6) AGE: 56

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

HEMOGLOBIN A1C

Hgb A1c 7.6

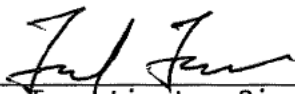
Normals:

4.3-6.1%

Stable Diabetics:

4.2-11.2%

17 Oct 2007



Investigator Signature:

17 Oct 2007
Date:

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VISIT: 15

Week 24/Early Term

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SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

CHEMISTRY PANEL

Total Bili	0.5		0.2-1.2 mg/dL
Alk Phos	79		35-131 U/L
ALT (SGPT)	66	H	6-43 U/L
AST (SGOT)	36		11-36 U/L
GGT	58		10-61 U/L
LDH	155		53-234 U/L
Urea Nitr	12		4-24 mg/dL
Creatinine	0.7		0.5-1.3 mg/dL
Glucose	185	H	70-115 mg/dL
Uric Acid	4.7		2.5-8.3 mg/dL
Calcium	9.5		8.3-10.6 mg/dL
Phosphorus	3.2		2.2-5.1 mg/dL
Total Prot	7.3		6.1-8.4 g/dL
Albumin	4.0		3.3-4.9 g/dL
Sodium	137		132-147 mEq/L
Potassium	4.1		3.4-5.4 mEq/L
Chloride	102		94-112 mEq/L

[]

[]

[]

[]

15 Oct 2007
Subject will F/U lab
with PEP.

Investigator Signature:

Date:

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 1900 Mason Ave

Daytona Beach, FL 32117

SPONSOR REPORT TO:

Russell M. Dixon, MD
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 Covance CRU, Inc.
 3402 Kinsman Boulevard

Madison, WI United States 53704

PROTOCOL 6270-229

INVESTIGATOR NO.: 3

RANDOMIZATION NUMBER: R3022

PATIENT INITIALS: (b) (6)

VISIT: 15

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SEX: M BIRTHDATE: (b) (6) AGE: 56

SCREENING NUMBER: S3084

Is this Clinically
 Significant/ Adverse
 Event?

Yes

No

HEMATOLOGY& DIFFERENTIAL PANEL

HGB	14.2		12.7-18.1 g/dL
HCT	42		39-54 %
RBC	4.3	L	4.5-6.4x10 ⁶ /uL
MCV	99	H	79-96 fL
MCH	33		26-34 pg
MCHC	34		31-38 g/dL
RDW	12.7		12.0-15.0 %
RBC Morph	Normocytic		
WBC	6.91		3.80-10.70 x10 ³ /uL
Neutrophil	4.02		1.96-7.23 x10 ³ /uL
Lymphocyte	2.33		0.91-4.28 x10 ³ /uL
Monocytes	0.42		0.12-0.92 x10 ³ /uL
Eosinophil	0.11		0.00-0.57 x10 ³ /uL
Basophils	0.02		0.00-0.20 x10 ³ /uL
Neutrophil	58.2		40.5-75.0 %
Lymphocyte	33.8		15.4-48.5%
Monocytes	6.1		2.6-10.1 %
Eosinophil	1.6		0.0-6.8 %
Basophils	0.3		0.0-2.0 %
Platelets	217		140-400 x10 ³ /uL

15 Oct 2007

Investigator Signature:

Date:

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Page 3 of 3

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VISIT: 15

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SEX: M BIRTHDATE: (b) (6) AGE: 56

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

URINE MACRO & MICRO PANEL

Color	Yellow
Clarity	Cloudy
Spec Grav	1.023
pH	5.5
Protein	Negative
Glucose	Trace H
Ketones	Negative
Bilirubin	Negative
Urobilin	Normal
Blood	Negative
Nitrite	Negative
Leuk Est	Negative
Microscop	Positive

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

[]

[X]

CRYSTALS

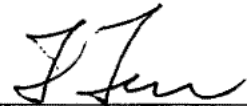
Uric Acid	Present	Ref Rng: Not present
-----------	---------	----------------------

MISCELLANEOUS ELEMENTS

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

NCS

15 Oct 2007


Investigator Signature:

17 Oct 2007
Date:

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PATIENT INITIALS: (b) (6)

VISIT: 15

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SEX: M BIRTHDATE: (b) (6) AGE: 56

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Is this Clinically
Significant/ Adverse
Event?

Yes

No

FIBRINOGEN - See Note #1

Fibrinogen Awaiting specimen arrival

15 Oct 2007

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

[Signature]
Investigator Signature:

17 Oct 2007
Date:

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

B20476

(INV)

Covance CLS

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Tel. +1 (800) 327 7270

LABORATORY REPORT

ACCESSION NO. Q514909

Page 1 of 1

INVESTIGATOR: (B20476)

Frank Farmer, Jr., M.D.

c/o Deborah Jacobsen

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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: R3022

PATIENT INITIALS: (b) (6)

VISIT: 15

Week 24/Early Term

COLLECTION TIME:10:06 DATE:12-Oct-2007

DATE RECEIVED IN LABORATORY: 13-Oct-2007

DATE REPORTED BY LABORATORY: 13-Oct-2007

SEX: M BIRTHDATE: (b) (6) AGE: 56

SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

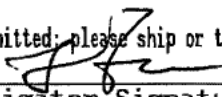
sICAM-1 - See Note #1

sICAM-1

Awaiting specimen arrival

15 Oct 2007

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


Investigator Signature:*17 Oct 2007*
Date:

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SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

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

15 Oct 2007

Note #1 - No specimen received

[Signature]
Investigator Signature:

17 Oct 2007
Date:

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Event?

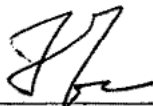
Yes

No

HAS PATIENT FASTED 8 HOURS?

Fasted?

Yes

15 Oct 2007

Investigator Signature:

17 Oct 2007
Date:

B20476

(INV)

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SCREENING NUMBER: S3084

Is this Clinically
Significant/ Adverse
Event?

Yes

No

OXIDIZED LDL - See Note #1

OxidizeLDL Awaiting specimen arrival

15 Oct 2007

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

[Signature]
Investigator Signature:

17 Oct 2007
Date:

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Testing performed by: Pacific Biometrics

220 West Harrison Street; Seattle, WA 98119

B20476

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Week 24/Early Term
COLLECTION TIME: 10:06 DATE: 12-Oct-2007
DATE RECEIVED IN LABORATORY: 13-Oct-2007
DATE REPORTED BY LABORATORY: 31-Mar-2008
SEX: M BIRTHDATE: (b) (6) AGE: 56
SCREENING NUMBER: S3084

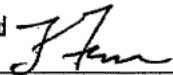
Is this Clinically
Significant/ Adverse
Event?
Yes No

TOTAL IRON
Total Iron 116 45-160 ug/dL

C-REACTIVE PROTEIN - See Note #1

CARBOXYHEMOGLOBIN - See Note #1

Note #1 - No specimen received


Investigator Signature:

01 APR 2008
Date:

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B20476

(INV)

04/01/2008 12:10:20 AM 0000 COVANCE CLS
Covance CLS
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LABORATORY REPORT

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Is this Clinically
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Event?
Yes No

HOMOCYSTEINE - See Note #1

Note #1 - No specimen received


Investigator Signature:

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Date:

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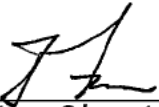
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Yes No

URINE CREATININE, SPOT - See Note #1

Note #1 - No specimen received


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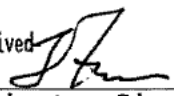
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SEX: M BIRTHDATE: (b) (6) AGE: 56
SCREENING NUMBER: S3084

Is this Clinically
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Event?

Yes No

LIPID PANEL - See Note #1

Note #1 - No specimen received


Investigator Signature:

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