

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 12:06:00

Report Parameters

Site: CDB_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R1012

Ending patient: R1012

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)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

Protocol Number SM 08-01 Investigator Name:
Study Site:

A CONTROLLED STUDY OF THE ABILITY OF A TRADITIONAL SWEDISH SMOKELESS TOBACCO PRODUCT ("SNUS") TO INCREASE THE QUIT RATE AMONG CIGARETTE SMOKERS WHO WISH TO STOP SMOKING

Protocol No. SM 08-01
Covance Study No. 7694-105

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

Covance Clinical Research Unit Inc.
3402 Kinsman Blvd
Madison, Wisconsin 53704

Verified Approved Locked Frozen

Page Version No. PAGE_01 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Inclusion Criteria

Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (check Yes or No)

- | | Yes/No* |
|---|------------------------------|
| <input type="checkbox"/> 01 The subject is male or female, between 25 and 65 years of age, inclusive. If female, the subject has a negative urine pregnancy test and is not lactating, or has not been of childbearing potential for at least 3 months prior to use of study product. To be considered to be not of childbearing potential, the subject must be postmenopausal for at least 2 years; have had a hysterectomy or bilateral tubal ligation, or be proven to be otherwise incapable of pregnancy. If of childbearing potential, the subject must have been practicing one of the following methods of contraception consistently for at least 1 month prior to study entry and agree to continue practicing it during the study: hormonal contraceptives, intrauterine device, spermicide and barrier, spouse/partner sterility; or is practicing abstinence and agrees to continue abstinence or to start an acceptable method of contraception from the above list if sexual activity commences. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 02 The subject smokes > 9 cigarettes per day (average daily consumption during past month). | <input type="checkbox"/> YES |
| <input type="checkbox"/> 03 The subject has smoked daily for >1 year. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 04 The subject is motivated to quit smoking with the help of a smokeless tobacco alternative. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 05 The subject is in good general health as evidenced by medical history, physical examination, routine blood chemistry (Hb, total WBC, transaminases, creatinine, electrolytes), and an ECG | <input type="checkbox"/> YES |
| <input type="checkbox"/> 06 The subject practices, by self-report, good oral hygiene (including brushing teeth at least twice per day and having regular dental check-ups). | <input type="checkbox"/> YES |
| <input type="checkbox"/> 07 The subject is able and willing to provide written informed consent. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 08 The subject agrees to comply with the requirements of the protocol and complete study measures. | <input type="checkbox"/> YES |
| <input type="checkbox"/> 09 The subject has stable residence and telephone. | <input type="checkbox"/> YES |

* If No, document on Subject Eligibility Page.

Verified Approved Locked Frozen

Page Version No. PAGE_02 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Exclusion Criteria

The following will exclude potential subjects from the study. Does the subject have any of the following? (Check Yes or No)

	Yes*/No
<input type="checkbox"/> 01 The subject is a current user of ST (defined as daily usage during more than 1 week within past 6 months) or is unable to refrain from NRT or any other non-protocol treatment during the study. Use of pipes, cigars, cigarillos, snuff, and chewing tobacco is also prohibited during the study.	<input type="checkbox"/> NO
<input type="checkbox"/> 02 The subject is a female who is pregnant or lactating.	<input type="checkbox"/> NO
<input type="checkbox"/> 03 The subject has oral conditions that could potentially be made worse by the use of study product, for instance, exposed dental services in the upper sulcus.	<input type="checkbox"/> NO
<input type="checkbox"/> 04 The subject has used any type of pharmaceutical (including some psychotropics, e.g., wellbutrin) or other products for smoking cessation within the past 3 months.	<input type="checkbox"/> NO
<input type="checkbox"/> 05 The subject has a history of clinically significant renal, hepatic, neurological, or chronic pulmonary disease that in the judgement of the investigator precludes participation.	<input type="checkbox"/> NO
<input type="checkbox"/> 06 The subject has a history of cardiovascular disease, including myocardial infarction within the last 3 months, significant cardiac arrhythmias, or poorly controlled hypertension (defined as a diastolic pressure of more than 90 mm Hg or a systolic pressure of more than 140 mm Hg) that in the judgment or the investigator precludes participation.	<input type="checkbox"/> NO
<input type="checkbox"/> 07 The subject has a history of alcohol or substance abuse or dependence other than cigarette smoking within the past year	<input type="checkbox"/> NO
<input type="checkbox"/> 08 Use of any illicit drug or smoked marijuana in the last 3 months	<input type="checkbox"/> NO
<input type="checkbox"/> 09 The subject is unwilling to be randomized into active or placebo conditions, or be available for follow-up assessments.	<input type="checkbox"/> NO
<input type="checkbox"/> 10 The subject resides in a household where another member is currently participating in the study.	<input type="checkbox"/> NO

* If Yes, document on Subject Eligibility Page.

Verified Approved Locked Frozen

Page Version No. PAGE_03 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

Date of Information Session: Did the subject attend the Information Session? Yes No (explain, if No) Comments

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

Did the subject meet all of the inclusion/exclusion criteria? Yes No

If the subject did not meet all of the Inclusion/Exclusion criteria, provide criterion number and explanation below.

Inclusion/Category	Exclusion No.	Explanation	Exemption Granted?	If Yes, Date Granted?
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Verified Approved Locked Frozen

Page Version No. PAGE_04 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="01-APR-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other		<input type="text"/>

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="67.0"/>

Verified Approved Locked Frozen

Page Version No. PAGE_05 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	106
Diastolic Blood Pressure	MMHG	076
Heart Rate	BEATS/MINUTE	063
Respiratory Rate	BREATHS/MINUTE	17
Body Temperature	C	36.6
Weight	LB	128.8

Verified Approved Locked Frozen

Page Version No. PAGE_06 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

Positive Negative N/A, Male or Woman of Non-childbearing Potential

Urine Drug Screen

Drug Screen Result*

Positive Negative

*If result derived from test performed by a clinical laboratory, attach copy of signed laboratory report to the CRF.

Verified Approved Locked Frozen

Page Version No. PAGE_07 (v1, 24-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="01-APR-2009"/>	<input type="text" value="10:22"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

Verified Approved Locked Frozen

Page Version No. PAGE_08 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	OCCASIONAL LEG CRAMPS	00-00-1970		<input checked="" type="checkbox"/> Ongoing
2	OCCASIONAL BODY ACHES	00-00-2004		<input checked="" type="checkbox"/> Ongoing
3	HEADACHE	29-MAR-2009	29-MAR-2009	<input type="checkbox"/> Ongoing
4	POSTMENOPAUSAL	00-MAR-2005		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

- * Skin
- * Ears, Eyes, Nose, Throat (EENT)
- * Breasts
- * Respiratory
- * Cardiovascular
- * Lymphatic/Hematologic
- * Gastrointestinal
- * Genitourinary
- * Musculoskeletal
- * Endocrine
- * Neurological
- * Immunological
- * Psychological
- * Allergies

Verified Approved Locked Frozen

Page Version No. PAGE_09 (v1, 24-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="15"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="20"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	COLD TURKEY

Verified Approved Locked Frozen

Page Version No. PAGE_10 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
01-APR-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
01-APR-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
01-APR-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_11 (v1, 24-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Physical Examinations

Date

Does the subject have any abnormal findings? Yes No

Sequence

No.	Findings
1	PARTIAL UPPER DENTURES
2	DERMATITIS OF ABDOMEN
3	TORUS ON ROOF OF MOUTH

Consider the following systems when performing the assessment:

- * Oral Cavity
- * Neck (including thyroid)
- * Extremities
- * General Apperance
- * Lungs
- * Neurologic/Nervous System
- * Skin
- * Heart
- * Lymph Nodes
- * HEENT
- * Abdomen

Verified Approved Locked Frozen

Page Version No. PAGE_12 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

Date	Parameter	Result	Comments
01-APR-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
01-APR-2009	WAS "CLEANING THE AIR" BOOKLET PROVIDED?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_13 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
16-APR-2009	12:45	33	5.9	

Behavioral Counseling

Date	Parameter	Result	Comments
16-APR-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire	Was Questionnaire Administered?
FTND	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
MNWS	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Verified Approved Locked Frozen

Page Version No. PAGE_14 (v1, 31-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time
Was Subject randomized? Yes No

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="8"/> logs
1.0 g of snus or matching placebo	<input type="text" value="4"/> logs

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_15 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="24-APR-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="01-MAY-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="08-MAY-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="56"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_16 (v1, 14-APR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?

Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_16 (v1, 14-APR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	107
Diastolic Blood Pressure	MMHG	076
Heart Rate	BEATS/MINUTE	081
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	36.7
Weight	LB	129.6

Verified Approved Locked Frozen

Page Version No. PAGE_17 (v1, 30-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

Page Version No. PAGE_18 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
29-MAY-2009	09:38	33	5.9	

Behavioral Counseling

Date	Parameter	Result	Comments
29-MAY-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_19 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product

Amount Dispensed

0.5 g of snus or matching placebo logs

1.0 g of snus or matching placebo logs

Status Review

Date

Parameter

Result

Comments

Was Subject's smoking status reviewed? Yes No

Was Subject compliant? Yes No

If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?

Was Subject asked HDYF? question? Yes No

Diary Distribution

Date

Did subject receive diary and usage instructions?

Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_20 (v1, 24-APR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
17-JUN-2009	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="105"/>	
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Verified Approved Locked Frozen

Page Version No. PAGE_21 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	094
Diastolic Blood Pressure	MMHG	060
Heart Rate	BEATS/MINUTE	078
Respiratory Rate	BREATHS/MINUTE	014
Body Temperature	C	037.0
Weight	LB	131.6

Verified Approved Locked Frozen

Page Version No. PAGE_22 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
29-JUN-2009	13:52	40	7.0	

Behavioral Counseling

Date	Parameter	Result	Comments
29-JUN-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_23 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="1"/> logs
1.0 g of snus or matching placebo	<input type="text" value="5"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="29-JUN-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="140"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_24 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="22-JUL-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="105"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_25 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

Verified Approved Locked Frozen

Page Version No. PAGE_26 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

Page Version No. PAGE_27 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_28 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
<input type="text"/>				

Behavioral Counseling

Date	Parameter	Result	Comments
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Questionnaires

Date

Questionnaire	Was Questionnaire Administered?
FTND	<input type="checkbox"/> Yes <input type="checkbox"/> No
MNWS	<input type="checkbox"/> Yes <input type="checkbox"/> No

Verified Approved Locked Frozen

Page Version No. PAGE_30 (v1, 31-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text"/>	Was Subject's smoking status reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_31 (v1, 12-MAY-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="105"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="105"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_32 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

Were vital signs collected? Yes No Date Actual Time Was Subject seated for 5 minutes? Yes No

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	104
Diastolic Blood Pressure	MMHG	070
Heart Rate	BEATS/MINUTE	073
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.6
Weight	LB	132.0

Verified Approved Locked Frozen

Page Version No. PAGE_33 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

Were there any clinically significant labs? Yes (specify below) No

Requisition Number	Test Name	Test Code ID
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

Page Version No. PAGE_34 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
<input type="text" value="29-OCT-2009"/>	<input type="text" value="EVIDENCE OF LEUKOPLAKIA"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="29-OCT-2009"/>	<input type="text" value="EXPOSED DENTAL CERVICES IN UPPER SULCUS?"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
<input type="text" value="29-OCT-2009"/>	<input type="text" value="OTHER ORAL KERATOSIS"/>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_35 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
29-OCT-2009	08:52	35	6.2	

Behavioral Counseling

Date	Parameter	Result	Comments
29-OCT-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

Questionnaire	Was Questionnaire Administered?
FTND	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
MNWS	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Verified Approved Locked Frozen

Page Version No. PAGE_37 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="29-OCT-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="140"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_38 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

Verified Approved Locked Frozen

Page Version No. PAGE_39 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

Verified Approved Locked Frozen

Page Version No. PAGE_39 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

Verified Approved Locked Frozen

Page Version No. PAGE_39 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

Verified Approved Locked Frozen

Page Version No. PAGE_39 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

- grams
- micrograms
- milligrams
- milliliter
- tablet
- other, specify

- one time
- whenever necessary
- every morning
- at bedtime
- every day
- twice daily

- three times daily
- four times daily
- every four hours
- every other day
- every week
- other, specify

Start Date1

Stop Date1

Ongoing

1Start and Stop Date: If medication is given on a regular schedule, report start date only once. If dose regimen changes, report a new line of information. Report start and stop dates for each change in dose regimen.

Verified Approved Locked Frozen

Page Version No. PAGE_39 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
 - Unlikely
 - Possibly Related
 - Probably Related
 - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

Verified Approved Locked Frozen

Page Version No. PAGE_40 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

Were any additional 12-lead ECGs collected? Yes, list below. No

Date	Actual Time	ECG Interpretation	Comments Regarding CS Findings:
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	<input type="text"/>

Verified Approved Locked Frozen

Page Version No. PAGE_41 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Additional Assessments - Laboratory Evaluations

Were any additional laboratory evaluations collected? Yes, list below No

Date	Requisition Number	Clinically Significant?	Test Name CS Labs Only	Test Code ID CS Labs Only	Comments
24-AUG-2009	NA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

Page Version No. PAGE_42 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

Were any additional vital signs collected? Yes, list below. No

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	099
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	071
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	074
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	12
	Body Temperature	C	036.6

Comments

Date Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure		
<input type="checkbox"/> Supine	Diastolic Blood Pressure		
<input type="checkbox"/> Seated	Heart Rate		
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate		
	Body Temperature		

Comments

Verified Approved Locked Frozen

Page Version No. PAGE_43 (v1, 27-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
24-AUG-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
24-AUG-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
24-AUG-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_45 (v1, 25-MAR-2009)

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

- NA, Completed Study
- Adverse Event, specify:
- Terminated by Sponsor
- Consent Withdrawn
- Lost to Follow-up
- Other, specify:

Investigator Comments (if none, leave blank):

By electronically approving this case report form, I have reviewed the data and found them to be complete and accurate.

Verified Approved Locked Frozen

Page Version No. PAGE_46 (v1, 25-MAR-2009)

Document Number

Appendix: Audit and Discrepancy Information

Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

Document #: **R243421513**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Screening	Page_07 07

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	7	Screening

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Were there any clinically significant la (1) 1	NO		06-JUL-2009 11:19:42 Rossana Matos	Data Entry Error

Document #: R243422113

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Screening	Page_09 09

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Mh	Page number	9	Screening

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Onset 1	00-00-1970	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Date of Resolution 1		02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Diagnosis/Procedure 1	LEG CRAMPS	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Diagnosis/Procedure 1	LEG CRAMPS OCCASIONAL LEG CRAMPS	01-MAR-2010 10:06:42 Christina Breedlove	Investigator Correction
Does the subject have any relevant medication 1	NO YES	27-NOV-2009 04:12:07 Rossana Matos	Data Entry Error
Ongoing 1	CHECKED	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Sequence Number 1	1	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Date of Onset 2	00-00-2004	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Date of Resolution 2		02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Diagnosis/Procedure 2	BODY ACHES	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Diagnosis/Procedure 2	BODY ACHES OCCASIONAL BODY ACHES	01-MAR-2010 10:06:42 Christina Breedlove	Investigator Correction
Ongoing 2	CHECKED	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted
Sequence Number 2	2	02-DEC-2009 11:24:56 Christina Breedlove	Row Inserted

Document #: **R243422113**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Screening	Page_09 09

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Mh	Page number	9	Screening

Group #	Group Name
2	MH1

Date of Onset		02-DEC-2009 11:24:56	Row Inserted
3	29-MAR-2009	Christina Breedlove	
Date of Resolution		02-DEC-2009 11:24:56	Row Inserted
3	29-MAR-2009	Christina Breedlove	
Diagnosis/Procedure		02-DEC-2009 11:24:56	Row Inserted
3	HEADACHE	Christina Breedlove	
Ongoing		02-DEC-2009 11:24:56	Row Inserted
3		Christina Breedlove	
Sequence Number		02-DEC-2009 11:24:56	Row Inserted
3	3	Christina Breedlove	
Date of Onset		23-FEB-2010 17:39:12	Row Inserted
4		Krysia Magnuson	
Date of Onset		01-MAR-2010 10:06:42	Validation Status changed
4	00-MAR-2005	Christina Breedlove	
Date of Resolution		23-FEB-2010 17:39:12	Row Inserted
4		Krysia Magnuson	
Diagnosis/Procedure		23-FEB-2010 17:39:12	Row Inserted
4		Krysia Magnuson	
Diagnosis/Procedure		01-MAR-2010 10:06:42	Validation Status changed
4	POSTMENOPAUSAL	Christina Breedlove	
Ongoing		23-FEB-2010 17:39:12	Row Inserted
4		Krysia Magnuson	
Ongoing		01-MAR-2010 10:06:42	Validation Status changed
4	CHECKED	Christina Breedlove	
Sequence Number		23-FEB-2010 17:39:12	Row Inserted
4		Krysia Magnuson	
Sequence Number		01-MAR-2010 10:06:42	Validation Status changed
4	4	Christina Breedlove	

Document #: **R243422213**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Screening	Page_10 10

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Smoking History	Page number	10	Screening

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Attempted to quit (Other attempts) (5) 1	NO YES	15-OCT-2009 12:58:30 Rossana Matos	Data Entry Error

Document #: **R243422613**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Screening	Page_12 12

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	12	Screening

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings 1	DERMATITIS OF ABDOMEN <Row Deleted>	10-NOV-2009 12:56:35 Rossana Matos	Data Entry Error
Findings 1	PARTIAL UPPER DENTURE (RELAVANT NCS) PER DR. FARMER	10-NOV-2009 12:56:35 Rossana Matos	Row Inserted
Findings 1	PARTIAL UPPER DENTURE (RELAVANT NCS) PER DR. FARMER PARTIAL UPPER DENTURES	31-DEC-2009 15:01:51 Sharon Daly	Data Entry Error
Sequence Number 1	1 <Row Deleted>	10-NOV-2009 12:56:35 Rossana Matos	Data Entry Error
Sequence Number 1	1	10-NOV-2009 12:56:35 Rossana Matos	Row Inserted
Findings 2	PARTIAL UPPER DENTURE <Row Deleted>	10-NOV-2009 12:56:35 Rossana Matos	Data Entry Error
Findings 2		17-DEC-2009 09:33:13 Heather Kretschmer	Row Inserted
Findings 2	DERMATITIS OF ABDOMEN	31-DEC-2009 15:01:51 Sharon Daly	Data Entry Error
Sequence Number 2	2 <Row Deleted>	10-NOV-2009 12:56:35 Rossana Matos	Data Entry Error
Sequence Number 2		17-DEC-2009 09:33:13 Heather Kretschmer	Row Inserted
Sequence Number 2	2	31-DEC-2009 15:01:51 Sharon Daly	Data Entry Error
Findings 3	TORUS ON ROOF OF MOUTH <Row Deleted>	10-NOV-2009 12:56:35 Rossana Matos	Data Entry Error
Findings 3	TORUS ON ROOF OF MOUTH	31-DEC-2009 15:01:51 Sharon Daly	Row Inserted
Sequence Number 3	3 <Row Deleted>	10-NOV-2009 12:56:35 Rossana Matos	Data Entry Error

Document #: **R243422613**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Screening	Page_12 12

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	12	Screening

Group #	Group Name
2	MH1

Sequence Number	31-DEC-2009 15:01:51	Row Inserted
3	3	Sharon Daly

Document #: **R243423413**

Patient Site	Visit Visit Date	CRF CRF Page		
R1012 CDB_001	Baseline, Week 0	Page_14 14		
Section Section Date	Qualifying Prompt	Qualifying Value		Section Visit
Questionnaires	Page number	14		Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
FTND 1	YES NO	09-JUN-2009 11:50:23 Sharon Daly	Pass1
FTND 1	NO YES	09-JUN-2009 11:50:36 Sharon Daly	Pass1

Document #: **R243423713**

Patient Site	Visit Visit Date	CRF CRF Page	
R1012 CDB_001	Baseline, Week 0	Page_15 15	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Sc	Page number	15	Baseline, Week 0

Group #	Group Name
1	SC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Was Subject randomized? 1	YES NO	09-JUN-2009 11:50:46 Sharon Daly	Pass1
Was Subject randomized? 1	NO YES	09-JUN-2009 11:50:59 Sharon Daly	Pass1

Document #: **R243441813**

Patient Site	Visit Visit Date	CRF CRF Page	
R1012 CDB_001	Sptp, Weeks 1-4	Page_16 16	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (10) 1	10 70	26-APR-2009 14:07:08 Rossana Matos	Pass1
Comments (how many cigarettes) (5) 1	PER DAY	26-APR-2009 14:07:08 Rossana Matos	Pass1

Document #: **R252826213**

Patient Site	Visit Visit Date	CRF CRF Page	
R1012 CDB_001	Ip, Week 6	Page_18 18	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	18	Ip, Week 6

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Requisition Number 1: (1) 1	NA	16-JUN-2009 08:46:04 Rossana Matos	Data Entry Error data clarification
Were there any clinically significant la (1) 1	NO	16-JUN-2009 08:46:04 Rossana Matos	Data Entry Error data clarification

Document #: **R265445413**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_26 26

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
----------------------	-------------------	------------------	---------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	10-MAR-2010 09:29:21 Christina Breedlove	Validation Status changed

Document #: **R265446713**

Patient Site	Visit Visit Date	CRF CRF Page
R1012	Ip, Week 16	Page_27
CDB_001		27

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
----------------------	-------------------	------------------	---------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	N	10-MAR-2010 09:13:36	Validation Status changed
1	Y	Christina Breedlove	Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.

Document #: **R265446913**

Patient Site	Visit Visit Date	CRF CRF Page
R1012	Ip, Week 16	Page_28
CDB_001		28

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
----------------------	-------------------	------------------	---------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	N	10-MAR-2010 09:15:50	Validation Status changed
1	Y	Christina Breedlove	Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.

Document #: **R265447313**

Patient Site	Visit Visit Date	CRF CRF Page
R1012	Ip, Week 16	Page_29
CDB_001		29

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
----------------------	-------------------	------------------	---------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	N	10-MAR-2010 09:17:34	Validation Status changed
1	Y	Christina Breedlove	Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.

Document #: **R265447313**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_29 29

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	29	Ip, Week 16

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	YES NO	02-DEC-2009 11:33:14 Christina Breedlove	Data Entry Error per query
Findings 1	DERMATITIS OF ABDOMEN	02-DEC-2009 11:33:14 Christina Breedlove	Data Entry Error
Sequence Number 1	1	02-DEC-2009 11:33:14 Christina Breedlove	Data Entry Error
Findings 2	TORUS ON ROOF OF MOUTH	02-DEC-2009 11:33:14 Christina Breedlove	Data Entry Error
Sequence Number 2	2	02-DEC-2009 11:33:14 Christina Breedlove	Data Entry Error
Findings 3	PARTIAL UPPER DENTURES	02-DEC-2009 11:33:14 Christina Breedlove	Data Entry Error
Sequence Number 3	3	02-DEC-2009 11:33:14 Christina Breedlove	Data Entry Error

Document #: **R265447813**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_30 30

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
----------------------	-------------------	------------------	---------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	10-MAR-2010 09:25:17 Christina Breedlove	Validation Status changed

Document #: **R265448213**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
----------------------	-------------------	------------------	---------------

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	17-MAR-2010 09:38:49 Christina Breedlove	Validation Status changed For visits that were not done or that were too far outside of the window, the CRF pages are marked blank.

Document #: R265448213

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (HDYF) (8) 1	SUBJECT CAME IN FOR WEEK 16 VISIT DURING THEIR WEEK 19. ALL WEEK 16 VISIT PROCEDURES WERE COMPLETED AT THIS TIME AND THE SUBJECT WAS ASKED HDYF.	02-DEC-2009 11:37:49 Christina Breedlove	Data Entry Error Subject was over 2 weeks late for week 16 site visit. Subject's week 16 visit occurred during their week 19.
Comments (HDYF) (8) 1	SUBJECT CAME IN FOR WEEK 16 VISIT DURING THEIR WEEK 19. ALL WEEK 16 VISIT PROCEDURES WERE COMPLETED AT THIS TIME AND THE SUBJECT WAS ASKED HDYF.	10-MAR-2010 09:19:46 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.
Date 1	24-AUG-2009 06-AUG-2009	02-DEC-2009 11:37:49 Christina Breedlove	Data Entry Error data transcribed from subject's week 16 diary. Subject was over 2 weeks late for week 16 site visit.

Document #: **R265448213**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

Group #	Group Name
1	CHKYN

Date			
1	06-AUG-2009	10-MAR-2010 09:19:46 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.

Date		10-MAR-2010 09:21:57 Christina Breedlove	Data Entry Error
1	06-AUG-2009		
If Subject was not compliant, approximat (5)	105	02-DEC-2009 11:37:49 Christina Breedlove	Data Entry Error data transcribed from subject's week 16 diary. Subject was over 2 weeks late for week 16 site visit.
1			

If Subject was not compliant, approximat (5)	105	10-MAR-2010 09:19:46 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.
1			

If Subject was not compliant, approximat (5)	105	10-MAR-2010 09:21:57 Christina Breedlove	Data Entry Error
1			

Document #: R265448213

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

Group #	Group Name
1	CHKYN

Was Subject asked HDYF? (8) 1	YES	10-MAR-2010 09:19:46 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.
Was Subject asked HDYF? (8) 1	YES	10-MAR-2010 09:21:57 Christina Breedlove	Data Entry Error
Was Subject compliant (4) 1	YES NO	02-DEC-2009 11:37:49 Christina Breedlove	Data Entry Error data transcribed from subject's week 16 diary. Subject was over 2 weeks late for week 16 site visit.
Was Subject compliant (4) 1	NO	10-MAR-2010 09:19:46 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.
Was Subject compliant (4) 1	NO	10-MAR-2010 09:21:57 Christina Breedlove	Data Entry Error

Document #: **R265448213**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

Group #	Group Name
1	CHKYN

Was Subject's smoking status reviewed (2) 1	YES	10-MAR-2010 09:19:46 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.
Was Subject's smoking status reviewed (2) 1	YES	10-MAR-2010 09:21:57 Christina Breedlove	Data Entry Error
Was Subject's use of study product review (3) 1	YES	10-MAR-2010 09:19:46 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.
Was Subject's use of study product review (3) 1	YES	10-MAR-2010 09:21:57 Christina Breedlove	Data Entry Error

Document #: **R265448213**

Patient Site	Visit Visit Date	CRF CRF Page	
R1012 CDB_001	Ip, Week 16	Page_31 31	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Diary	Page number	31	Ip, Week 16

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCM Blank flag 1	N Y	10-MAR-2010 09:21:57 Christina Breedlove	CRA Correction per query

Document #: **R277578413**

Patient Site	Visit Visit Date	CRF CRF Page	
R1012 CDB_001	Fu, Week 28	Page_33 33	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	33	Fu, Week 28

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	0844 0849	02-DEC-2009 11:50:17 Christina Breedlove	Data Entry Error time confirmed to be 08:49

Document #: **R254182913**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Pcm	Page_39 39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Code 1	A12	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Text 1	MINERAL SUPPLEMENTS, A12	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Code 1	A12A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Text 1	CALCIUM, A12A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Code 1	A12AX	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Text 1	CALCIUM, COMBINATIONS WITH OTHER DRUGS, A12AX	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	CALCIUM/D CALCIUM D	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	CALCIUM/D CALCIUM D	09-APR-2010 11:48:03 Joanne Mccaigue	ODM/SEC Obvious spelling error. JLM 09Apr2010
Preferred Term 1	CALCIUM D3 /01483701/	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Preferred Term Code 1	01483701001	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Trade Name 1	CALCIUM & VITAMIN D	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Trade Name Code 1	01483701100	26-APR-2010 10:36:00 Carol Kraucyk	Data Change

Document #: **R254184013**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Pcm.3	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.3

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: **R254184213**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Pcm.4	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.4

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: **R282790413**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Additional Lab	Page_42 42

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	42	Additional Lab

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Clinically Significant (additional) (2) 1	NO	10-MAR-2010 09:11:27 Christina Breedlove	Row Inserted
Comments 1		10-MAR-2010 09:11:27 Christina Breedlove	Row Inserted
Date 1	24-AUG-2009	10-MAR-2010 09:11:27 Christina Breedlove	Row Inserted
Requisition Number (additional labs) (4) 1	NA	10-MAR-2010 09:11:27 Christina Breedlove	Row Inserted
Test Code ID CS Labs only 1		10-MAR-2010 09:11:27 Christina Breedlove	Row Inserted
Test Name CS Labs only 1		10-MAR-2010 09:11:27 Christina Breedlove	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES	10-MAR-2010 09:11:27 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.

Document #: R282790713

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Additional Vs	Page_43 43

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	43	Additional Vs

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	0832	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Body Temperature 1	036.6	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Body Temperature Unit 1	C	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Comments (2) 1		10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Date 1	24-AUG-2009	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Diastolic Blood Pressure 1	071	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Diastolic Blood Pressure unit 1	MMHG	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Heart Rate 1	074	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Heart Rate Unit 1	BEATS/MINUTE	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Other, specify (1) 1		10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Position (Unscheduled) (2) 1	SEATED	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Respiratory Rate 1	12	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
Respiratory Rate Unit 1	BREATHS/MINUTE	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted

Document #: **R282790713**

Patient Site	Visit Visit Date	CRF CRF Page
R1012 CDB_001	Additional Vs	Page_43 43

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	43	Additional Vs

Group #	Group Name
1	VS

Systolic Blood Pressure 1	099	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
------------------------------	-----	---	--------------

Systolic Blood Pressure unit 1	MMHG	10-MAR-2010 09:27:11 Christina Breedlove	Row Inserted
-----------------------------------	------	---	--------------

Were Vital Signs Collected/Were any addi (1) 1	NO YES	10-MAR-2010 09:27:11 Christina Breedlove	Validation Status changed Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.
---	-----------	---	--

Document #: **R282790813**

Patient	Visit	CRF
Site	Visit Date	CRF Page
R1012	Additional Pe	Page_44
CDB_001		44

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

Group #	Group Name
0	CRF Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCI Blank Flag	Y		10-MAR-2010 09:16:57	Validation Status changed
1	N		Christina Breedlove	Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.

Document #: **R282790913**

Patient Site	Visit	CRF
R1012	Oral Health Exam	Page_45
CDB_001		45

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			

Group #	Group Name
0	CRF Header

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
DCI Blank Flag	Y		10-MAR-2010 09:14:55	Validation Status changed
1	N		Christina Breedlove	Per new information rec'd on 09/Mar/10. Visits outside of the protocol window will be marked blank and data will be captured on additional pages. If there isn't an add'l pg data will be lost.

Discrepancy Detail Report

Document #: **R243421513**

Discrepancy ID: 1679228213 Site: CDB_001 Patient: R1012
Visit: SCREENING Visit Date:
CRF: PAGE_07 Section: LB Qualifying Value: 7
Field: Were there any clinically significant la Row: 1
Value Text: NO
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please complete entry.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R243422113

Discrepancy ID: 73237411 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 1
Value Text: OCCASIONAL LEG CRAMPS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update diagnosis/procedure term to clarify if this is an intermittent/episodic condition or a continuous chronic condition.
Internal Comment: Per query
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 73237511 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 2
Value Text: OCCASIONAL BODY ACHES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update diagnosis/procedure term to clarify if this is an intermittent/episodic condition or a continuous chronic condition.
Internal Comment: Per query
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 78147911 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 3
Value Text: HEADACHE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify removing Headache from Medical History as it occurred prior to Screening.
Internal Comment: Medical History conditions that are currently ongoing or that require medication at the start of the study or throughout the duration of the study should be considered relevant. Per the protocol, capture all con meds 30 days prior to screening. The subject took Ibuprofen on 29/Mar/2009. Confirmed with Investigator that headache should remain as part of this subject's medical history.
Resolution Type: No Action Required
Resolution Text:

R243422113

Discrepancy ID: 73235111 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 4
Value Text: POSTMENOPAUSAL
Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify Gender (female) and Urine Pregnancy Test Result (N/A, Male or Woman of Non-childbearing potential). If gender and pregnancy result are correct, please update medical history as a corresponding medical history event must be recorded to show why the subject is of non-childbearing potential.

Internal Comment: Per query- WONCBP-postmenopausal since 2005.

Resolution Type: Data value changed. Disc no longer applicable.

Resolution Text:

Discrepancy ID: 1789561813 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Does the subject have any relevant medic **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify per con med source "headache" should be added to med hx as a con med was taken, but headache occurred prior to screening.

Internal Comment: Add headache per con med sheet

Resolution Type: Confirmed

Resolution Text: Add headache per con med sheet

Discrepancy ID: 1789561713 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify general body aches should be added to med hx as subject takes con meds for this (see con med sheet).

Internal Comment: Added leg cramps and body aches as ongoing per med hx and con med forms.

Resolution Type: Confirmed

Resolution Text: Added leg cramps and body aches as ongoing per med hx and con med forms.

Document #: R243422613

Discrepancy ID: 1789444013 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_12 **Section:** PE **Qualifying Value:** 12
Field: Does the subject have any abnormal findi **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify per source findings are not relevant and should be removed.
Internal Comment:
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 21799311 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_12 **Section:** PE **Qualifying Value:** 12
Field: Findings **Row:** 1
Value Text: PARTIAL UPPER DENTURES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please delete "relevant NCS per Dr. Farmer".
Internal Comment: will delete
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 21799411 **Site:** CDB_001 **Patient:** R1012
Visit: SCREENING **Visit Date:**
CRF: PAGE_12 **Section:** PE **Qualifying Value:** 12
Field: Findings **Row:** 2
Value Text: DERMATITIS OF ABDOMEN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: per guidelines please add dermatitiis of abdomen and torus on roof of mouth.
Internal Comment: will add
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R277578413

Discrepancy ID: 1789553213 **Site:** CDB_001 **Patient:** R1012
Visit: FU, WEEK 28 **Visit Date:**
CRF: PAGE_33 **Section:** VS **Qualifying Value:** 33
Field: Actual Time **Row:** 1
Value Text: 0849
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify time of vital signs per source should be 0849.
Internal Comment: time confirmed to be 08:49
Resolution Type: Confirmed
Resolution Text: time confirmed to be 08:49

Deleted CRFs Report