

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 15:30:04

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2016

Ending patient: R2016

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

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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.

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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.

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Page Version No. PAGE_03 (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

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	

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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="24-APR-2009"/>	<input type="text" value="(b) (6)"/>	<input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	<input type="checkbox"/> Hispanic or Latino <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="71.1"/>

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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	136
Diastolic Blood Pressure	MMHG	084
Heart Rate	BEATS/MINUTE	068
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.6
Weight	LB	254.8

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Page Version No. PAGE_06 (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

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.

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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="24-APR-2009"/>	<input type="text" value="16:22"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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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	
01	HIGH BLOOD PRESSURE	00-00-2008		<input checked="" type="checkbox"/> Ongoing
02	HIGH CHOLESTEROL	00-00-2008		<input checked="" type="checkbox"/> Ongoing
03	SHORTNESS OF BREATH UPON EXERTION DUE	00-00-2006		<input checked="" type="checkbox"/> Ongoing
04	OSTEOARTHRITIS	00-00-2009		<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

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

Document Number

OverFlow Section For Document Number R252109413

1 SHORTNESS OF BREATH UPON EXERTION DUE TO STRENUOUS ACTIVITY

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="17"/>	
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="3"/>	LOZENGE 2006, 2007, 2008
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="1"/>	COLD TURKEY THROUGH 1994 -2000

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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](#)

[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

Oral Health Examination

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

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Page Version No. PAGE_11 (v1, 24-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

Behavioral Counseling

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

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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
08-MAY-2009	10:23	6	1.5	

Behavioral Counseling

Date	Parameter	Result	Comments
08-MAY-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

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Page Version No. PAGE_14 (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

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

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Page Version No. PAGE_15 (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	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="18-MAY-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="21"/>	<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="22-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="21"/>	<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="29-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="28"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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

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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

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	124
Diastolic Blood Pressure	MMHG	075
Heart Rate	BEATS/MINUTE	066
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.0
Weight	LB	258.0

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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.

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Page Version No. PAGE_18 (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
19-JUN-2009	16:04	1	0.7	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Page Version No. PAGE_19 (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="0"/> logs
1.0 g of snus or matching placebo	<input type="text" value="2"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="19-JUN-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="UNK"/>	<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?
<input type="text" value="19-JUN-2009"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Verified Approved Locked Frozen

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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="02-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 checked="" 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 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"/>

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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	125
Diastolic Blood Pressure	MMHG	075
Heart Rate	BEATS/MINUTE	068
Respiratory Rate	BREATHS/MINUTE	22
Body Temperature	C	36.5
Weight	LB	265.4

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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
17-JUL-2009	13:19	2	0.9	

Behavioral Counseling

Date	Parameter	Result	Comments
17-JUL-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="0"/> logs
1.0 g of snus or matching placebo	<input type="text" value="3"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="17-JUL-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="UNK"/>	<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

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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="07-AUG-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="5"/>	<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	MMHG	134
Diastolic Blood Pressure	MMHG	084
Heart Rate	BEATS/MINUTE	066
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.7
Weight	LB	267.2

Verified Approved Locked Frozen

Page Version No. PAGE_26 (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

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

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-SEP-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
01-SEP-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
01-SEP-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_28 (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
01-SEP-2009	13:29	2	0.9	

Behavioral Counseling

Date	Parameter	Result	Comments
01-SEP-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_30 (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
01-SEP-2009	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="49"/>	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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="20"/>	<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="35"/>	<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	111
Diastolic Blood Pressure	MMHG	072
Heart Rate	BEATS/MINUTE	074
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.7
Weight	LB	263.0

Verified Approved Locked Frozen

Page Version No. PAGE_33 (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

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="20-NOV-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="20-NOV-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="20-NOV-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
20-NOV-2009	13:22	1	0.7	

Behavioral Counseling

Date	Parameter	Result	Comments
20-NOV-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="20-NOV-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="35"/>	<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

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

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](#)

[Click here to navigate to discrepancy details 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

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](#)

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number R2016

Covance Study Number: 7694-105

Subject Initials (b)

Visit Name PCM

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: LIPITOR

Indication: HIGH CHOLESTEROL

Dose: 10

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

18-OCT-2009

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 R283615213

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

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 - 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

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

Page Version No. PAGE_42 (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 - 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		
<input type="checkbox"/> Supine	Diastolic Blood Pressure		
<input type="checkbox"/> Seated	Heart Rate		
<input type="checkbox"/> Other, specify	Respiratory Rate		
<input type="text"/>	Body Temperature		

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	Respiratory Rate		
<input type="text"/>	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](#)

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_45 (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

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 #: R246042213

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Screening	Page_03 03

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ec	Page number	3	Screening

Group #	Group Name
1	IE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Exclusion Criteria Answer 2	NAM NO	26-FEB-2010 15:18:39 Amanda Lynn	Data Entry Error

Document #: R246043813

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Screening	Page_07 07

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	22-SEP-2009 12:06:26 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	22-SEP-2009 12:07:08 Amanda Lynn	Data Entry Error

Document #: R246043813

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	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
Date 1	24-APR-2009		22-SEP-2009 12:07:08 Amanda Lynn	Row Inserted
No (Specify samples not done, reason)/Co 1			22-SEP-2009 12:07:08 Amanda Lynn	Row Inserted
Requisition Number 1: (1) 1	11468500150		22-SEP-2009 12:07:08 Amanda Lynn	Row Inserted
Requisition Number 2 (if applicable): (2) 1			22-SEP-2009 12:07:08 Amanda Lynn	Row Inserted
Requisition Number 3 (if applicable): (3) 1			22-SEP-2009 12:07:08 Amanda Lynn	Row Inserted
Were the scheduled laboratory samples ob 1	YES		22-SEP-2009 12:07:08 Amanda Lynn	Row Inserted
Were there any clinically significant la (1) 1	NO		22-SEP-2009 12:07:08 Amanda Lynn	Row Inserted

Document #: R252109413

Patient Site	Visit	CRF
R2016	Visit Date	CRF Page
L0689282_2	Screening	Page_09
		09

Section	Qualifying Prompt	Qualifying Value	Section Visit
Section Date			
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 3	00-00-2006	10-MAR-2010 10:02:37 Amanda Lynn	Data Entry Error
Date of Onset 3	<Row Deleted>	5->4;4->3 24-MAR-2010 15:32:39 Kryisia Magnuson	Data Entry Error
Date of Resolution 3	<Row Deleted>	5->4;4->3 24-MAR-2010 15:32:39 Kryisia Magnuson	Data Entry Error
Diagnosis/Procedure 3	SHORTNESS OF BREATH DUE TO STRENOUS ACTIVITY SHORTNESS OF BREATH DUE TO STRENUOUS ACTIVITY	24-FEB-2010 14:14:36 Kryisia Magnuson	ODM/SEC Strenous to Strenuous.
Diagnosis/Procedure 3	SHORTNESS OF BREATH DUE TO STRENUOUS ACTIVITY	10-MAR-2010 10:02:37 Amanda Lynn	Data Entry Error
Diagnosis/Procedure 3	<Row Deleted>	5->4;4->3 24-MAR-2010 15:32:39 Kryisia Magnuson	Data Entry Error
Diagnosis/Procedure 3	SHORTNESS OF BREATH UPON EXERTION DUE TO STRENOUS ACTIVITY SHORTNESS OF BREATH UPON EXERTION DUE TO STRENUOUS ACTIVITY	24-FEB-2010 14:14:36 Kryisia Magnuson	ODM/SEC Strenous to Strenuous.
Ongoing 3	CHECKED	10-MAR-2010 10:02:37 Amanda Lynn	Data Entry Error
Ongoing 3	<Row Deleted>	5->4;4->3 24-MAR-2010 15:32:39 Kryisia Magnuson	Data Entry Error
Sequence Number 3	03	10-MAR-2010 10:02:37 Amanda Lynn	Data Entry Error
Sequence Number 3	<Row Deleted>	5->4;4->3 24-MAR-2010 15:32:39 Kryisia Magnuson	Data Entry Error
Sequence Number 3	04	10-MAR-2010 10:02:37 Amanda Lynn	Data Entry Error
Sequence Number 4	05	10-MAR-2010 10:02:37 Amanda Lynn	Data Entry Error
	04		

Document #: R246045113

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	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 resequence	On By	Reason Comment
Comments (NRT) (4) 1	LOENGE 2006, 2007, 2008 LOZENGE 2006, 2007, 2008		08-MAR-2010 14:22:16 Kryisia Magnuson	ODM/SEC Loenge to Lozenge. KAY 08Mar2010.
If yes, how many (other attempts to quit (6)) 1	SEVERAL 1		22-SEP-2009 12:07:59 Amanda Lynn	Data Entry Error

Document #: R246046613

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Screening	Page_11 11

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Oral Health Exam	Page number	11	Screening

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings* 3	NE NO	11-JUN-2009 16:01:03 Amanda Lynn	Data Entry Error

Document #: R263844213

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Ip, Week 6	Page_20 20

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	20	Ip, Week 6

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
If Subject was not compliant, approximat (5) 1	40		23-OCT-2009 15:01:40 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	UNK		15-DEC-2009 10:12:12 Amanda Lynn	Data Entry Error
Was Subject compliant (4) 1	NO YES		23-OCT-2009 15:01:40 Amanda Lynn	Data Entry Error
Was Subject compliant (4) 1	YES NO		15-DEC-2009 10:12:12 Amanda Lynn	Data Entry Error

Document #: R263848113

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Ip, Week 10	Page_24 24

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	24	Ip, Week 10

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
If Subject was not compliant, approximat (5) 1	3		23-OCT-2009 15:02:21 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	UNK		15-DEC-2009 10:14:53 Amanda Lynn	Data Entry Error
Was Subject compliant (4) 1	NO YES		23-OCT-2009 15:02:21 Amanda Lynn	Data Entry Error
Was Subject compliant (4) 1	YES NO		15-DEC-2009 10:14:53 Amanda Lynn	Data Entry Error

Document #: R270750513

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	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	NO YES	22-SEP-2009 12:12:21 Amanda Lynn	Pass1
Does the subject have any abnormal findi 1	YES NO	22-SEP-2009 12:12:27 Amanda Lynn	Pass1

Document #: R270751113

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	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
If Subject was not compliant, approximat (5) 1	56 49	23-OCT-2009 15:03:43 Amanda Lynn	Data Entry Error

Document #: R246055713

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Pcm.2	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.2

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	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	A11	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	VITAMINS, A11	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	A11A	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	MULTIVITAMINS, COMBINATIONS, A11A	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	A11AB	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	MULTIVITAMINS, OTHER COMBINATIONS, A11AB	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Indication 1	PREVATATIVE SUPPLEMENT PREVENTATIVE SUPPLEMENT	09-APR-2010 15:04:21 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010
Preferred Term 1	MULTIVITAMINS	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	00116001001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

Document #: R246056513

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	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	V	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC1 Text 1	VARIOUS, V	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Code 1	V07	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Text 1	ALL OTHER NON-THERAPEUTIC PRODUCTS, V07	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Code 1	V07A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Text 1	ALL OTHER NON-THERAPEUTIC PRODUCTS, V07A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	EXTREME TRIM XTREME TRIM	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	EXTREME TRIM XTREME TRIM	09-APR-2010 15:04:47 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010
Preferred Term 1	ALL OTHER NON-THERAPEUTIC PRODUCTS	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Preferred Term Code 1	90047501001	26-APR-2010 10:36:00 Carol Kraucyk	Data Change

Document #: R246058413

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	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
Ongoing 1	CHECKED	20-OCT-2009 10:32:57 Amanda Lynn	Data Entry Error
Stop Date 1	00-JUN-2009	20-OCT-2009 10:32:57 Amanda Lynn	Data Entry Error

Document #: R246060513

Patient	Visit	CRF
Site	Visit Date	CRF Page
R2016	Pcm.5	Page_39
L0689282_2		

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	N	12-APR-2010	12:32:13	Data Entry Error
1	Y	Amanda Lynn		

Document #: R246063013

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Pcm.6	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.6

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
Indication 1	OSTEOARTHRITIS PAIN RELATED TO OSTEOARTHRITIS	22-OCT-2009 14:23:53 Amanda Lynn	Data Entry Error

Document #: R248768313

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Ae	Page_40 40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Adverse Event 1	BURNING SENSATION ON GUMS GINGIVAL DISCOMFORT		13-AUG-2009 13:53:50 Amanda Lynn	Pass1

Document #: R283616213

Patient Site	Visit Visit Date	CRF CRF Page
R2016 L0689282_2	Additional Pe	Page_44 44

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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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	08-DEC-2009 15:16:28 Amanda Lynn	Data Entry Error

Document #: R246043813

Discrepancy ID: 1737297413

Site: L0689282_2

Patient: R2016

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: UPREG

Qualifying Value: 7

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please complete

Internal Comment:

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

Resolution Text:

Document #: R246043813

Discrepancy ID: 1737299713

Site: L0689282_2

Patient: R2016

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: DRGSCR

Qualifying Value: 7

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please complete

Internal Comment:

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

Resolution Text:

Document #: R246045113

Discrepancy ID: 1737302413 **Site:** L0689282_2 **Patient:** R2016
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: Comments (other attempts) **Row:** 1
Value Text: COLD TURKEY THROUGH 1994 -2000
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update comment text (per DCF 7137302413) to clarify that the subject successfully quit for the years listed. (e.g. "Subject successfully quit from 1994-2000 using the cold turkey method".
Internal Comment: I can't that comment is not on our source so I cannot write that. Please leave as is.
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 1737302313 **Site:** L0689282_2 **Patient:** R2016
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: If yes, how many (other attempts to quit) **Row:** 1
Value Text: 1
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update after source has been clarified
Internal Comment: Per progress note on 24Apr2009, subject quit for 6 yrs cold turkey. # of times is = to 1
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R263844213

Discrepancy ID: 1790986813

Site: L0689282_2

Patient: R2016

Visit: IP, WEEK 6

Visit Date:

CRF: PAGE_20

Section: STATUS REVIEW

Qualifying Value: 20

Field: Was Subject compliant

Row: 1

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per return questionnaire subject smoked the week prior to wk 6 clinic visit. Wk 6 diary however states that no cigarettes were smoked. Please clarify.

Internal Comment:

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

Resolution Text:

Document #: R263848113

Discrepancy ID: 1790987113

Site: L0689282_2

Patient: R2016

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_24

Section: STATUS REVIEW

Qualifying Value: 24

Field: Was Subject compliant

Row: 1

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per return questionnaire, subject smoked cigarettes and was given instructions regarding quitting. Please verify number of cigarettes and compliance. Diary and questionnaire do not match.

Internal Comment:

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

Resolution Text:

Document #: R246058413

Discrepancy ID: 1737330713 **Site:** L0689282_2 **Patient:** R2016
Visit: PCM.4 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Stop Date **Row:** 1
Value Text: 200906
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review if medication was stopped on 00-Jun-2009
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R246063013

Discrepancy ID: 1737330913 **Site:** L0689282_2 **Patient:** R2016
Visit: PCM.6 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: PAIN RELATED TO OSTEOARTHRITIS
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review if ibuprofen was given for oesteoarthritis or for pain related to oesteoarthritis

Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Deleted CRFs Report