

# CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 09:58:28

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4045

Ending patient: R4045

## Legend: How different values appear in the report

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

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

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



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

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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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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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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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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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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  Male  Female

Ethnicity  Hispanic or Latino  Not Hispanic or latino

Race  White  Black or African American  Asian

Native Hawaiian or Other Pacific Islander  American Indian/Alaskan Native  Other

Body Measurements

Were Body Measurements Collected?  Yes  No Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="68.4"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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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	121
Diastolic Blood Pressure	MMHG	82
Heart Rate	BEATS/MINUTE	70
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.7
Weight	LB	156.6

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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.

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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="28-APR-2009"/>	<input type="text" value="09:38"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

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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	HOT FLASHES	00-AUG-2008		<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
				<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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## **Links to Discrepancy and Audit Sections**

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Swedish Match AB

Protocol Number: SM 08-01

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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="14"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="16"/>	
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	CHANTIX
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

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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
28-APR-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
28-APR-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
28-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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## **Links to Discrepancy and Audit Sections**

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Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

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

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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
05-MAY-2009	14:38	32	5.7	

Behavioral Counseling

Date	Parameter	Result	Comments
05-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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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

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Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="13-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="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="19-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="84"/>	<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="26-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="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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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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	86
Heart Rate	BEATS/MINUTE	65
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.6
Weight	LB	157.0

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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.

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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-JUN-2009	08:24	3	1.1	

Behavioral Counseling

Date	Parameter	Result	Comments
16-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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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	<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="16-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="14"/>	<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

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## **Links to Discrepancy and Audit Sections**

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="30-JUN-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="4"/>	<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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## **Links to Discrepancy and Audit Sections**

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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	109
Diastolic Blood Pressure	MMHG	70
Heart Rate	BEATS/MINUTE	72
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.2
Weight	LB	158.8

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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
14-JUL-2009	14:58	9	2.8	

Behavioral Counseling

Date	Parameter	Result	Comments
14-JUL-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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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="14-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="21"/>	<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

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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="03-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="21"/>	<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"/>

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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	110
Diastolic Blood Pressure	MMHG	69
Heart Rate	BEATS/MINUTE	65
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.7
Weight	LB	160.0

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Page Version No. PAGE\_26 (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: 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\_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
25-AUG-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
25-AUG-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
25-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.

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Page Version No. PAGE\_28 (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
25-AUG-2009	09:12	8	1.9	

Behavioral Counseling

Date	Parameter	Result	Comments
25-AUG-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\_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
<input type="text" value="25-AUG-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="42"/>	
	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

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Page Version No. PAGE\_31 (v1, 12-MAY-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
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="70"/>	<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="112"/>	<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\_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	102
Diastolic Blood Pressure	MMHG	66
Heart Rate	BEATS/MINUTE	74
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.7
Weight	LB	159.6

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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.

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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
17-NOV-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
17-NOV-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
17-NOV-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\_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
17-NOV-2009	08:39	14	2.8	

Behavioral Counseling

Date	Parameter	Result	Comments
17-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

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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="17-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="126"/>	<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\_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.

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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.

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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.

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

[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](#)

[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](#)

[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

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

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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

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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](#)

[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

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

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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

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Page Version No. PAGE\_40 (v1, 27-MAR-2009)

Document Number

## **Links to Discrepancy and Audit Sections**

[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

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"/>

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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.

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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

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Page Version No. PAGE\_43 (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

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.

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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 #: R296065213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4045 P3880_0342	Screening	Page_09 09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	9	Screening

<b>Group #</b>	<b>Group Name</b>
2	MH1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Date of Onset 1	10-JUN-2009 <Row Deleted>	3->2;2->1	04-MAR-2010 13:25:58 Lana Glaser	Data Entry Error
Date of Onset 1	28-JUL-2009 <Row Deleted>	2->1	04-MAR-2010 13:54:59 Kim Freschly	Data Entry Error
Date of Resolution 1	10-SEP-2009 <Row Deleted>	3->2;2->1	04-MAR-2010 13:25:58 Lana Glaser	Data Entry Error
Date of Resolution 1	04-AUG-2009 <Row Deleted>	2->1	04-MAR-2010 13:54:59 Kim Freschly	Data Entry Error
Diagnosis/Procedure 1	INSOMNIA <Row Deleted>	3->2;2->1	04-MAR-2010 13:25:58 Lana Glaser	Data Entry Error
Diagnosis/Procedure 1	HEADACHE OCCASIONAL <Row Deleted>	2->1	04-MAR-2010 13:54:59 Kim Freschly	Data Entry Error
Ongoing 1	<Row Deleted>	3->2;2->1	04-MAR-2010 13:25:58 Lana Glaser	Data Entry Error
Ongoing 1	<Row Deleted>	2->1	04-MAR-2010 13:54:59 Kim Freschly	Data Entry Error
Sequence Number 1	1 <Row Deleted>	3->2;2->1	04-MAR-2010 13:25:58 Lana Glaser	Data Entry Error
Sequence Number 1	2 1		04-MAR-2010 13:29:10 Lana Glaser	Data Entry Error
Sequence Number 1	1 <Row Deleted>	2->1	04-MAR-2010 13:54:59 Kim Freschly	Data Entry Error
Sequence Number 1	3 2		04-MAR-2010 13:29:10 Lana Glaser	Data Entry Error
Sequence Number 1	2 1		04-MAR-2010 13:54:59 Kim Freschly	Data Entry Error
Diagnosis/Procedure 2	HEADACHE HEADACHE OCCASIONAL		01-MAR-2010 11:14:46 Kim Freschly	Data Entry Error

**Document #:** R257304413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4045 P3880_0342	Screening	Page_10 10

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Smoking History	Page number	10	Screening

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Comments (other attempts) (7) 1	COLD TURKEY	01-SEP-2009 10:53:42 Lana Glaser	Data Entry Error

**Document #:** R257306013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4045 P3880_0342	Ip, Week 6	Page_20 20

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	20	Ip, Week 6

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	21 14	14-JAN-2010 13:59:23 Kim Freschly	Data Entry Error

**Document #:** R257306213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4045 P3880_0342	Ip, Week 8	Page_21 21

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	21	Ip, Week 8

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	2 4	09-JUL-2009 13:50:48 Kim Freschly	Data Entry Error

Document #: R266549113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4045 P3880_0342	Pcm.3	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.3

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
ATC1 Code 1	C	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	C01	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	CARDIAC THERAPY, C01	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	C01E	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STEROIDS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	C01EB	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change

Document #: R266549113

Patient Site	Visit Visit Date	CRF CRF Page
R4045 P3880_0342	Pcm.3	Page_39

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

Group #	Group Name
1	CM1

ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
Frequency 1	WHENEVER NECESSARY	14-JAN-2010 14:05:40 Kim Freschly	Data Entry Error
Preferred Term 1	IBUPROFEN	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
Preferred Term Code 1	00109201001	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
Stop Date 1	04-AUG-2009	14-JAN-2010 14:05:40 Kim Freschly	Data Entry Error
Trade Name 1	ADVIL /00109201/	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
Trade Name Code 1	00109201030	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change

Document #: R266549913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4045 P3880_0342	Pcm.4	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.4

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
ATC1 Code 1	V	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC1 Text 1	VARIOUS, V	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Code 1	V07	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Text 1	ALL OTHER NON-THERAPEUTIC PRODUCTS, V07	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Code 1	V07A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Text 1	ALL OTHER NON-THERAPEUTIC PRODUCTS, V07A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
Preferred Term 1	ALL OTHER NON-THERAPEUTIC PRODUCTS	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
Preferred Term Code 1	90047501001	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change

**Document #:** R266547213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4045 P3880_0342	Ae.1	Page_40

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Ae	Page number	40	Ae.1

<b>Group #</b>	<b>Group Name</b>
1	AE1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Resolved Date 1	21-JUN-2009 21-JUL-2009	04-MAR-2010 11:29:03 Kim Freschly	Data Entry Error

# Discrepancy Detail Report

Document #: R288104913

Discrepancy ID: 76577811

Site: P3880\_0342

Patient: R4045

Visit: SCREENING

Visit Date:

CRF: PAGE\_12

Section: PE

Qualifying Value: 12

Field: Findings

Row: 2

Value Text: "STY" LEFT UPPER LID

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: No data changes required.

Internal Comment: Please footnote on PE that there is no information regarding resolution or continuation of this sty over 2 additional physical exams.

Resolution Type: Confirmed

Resolution Text: FOOTNOTE ADDED TO SOURCE

**Document #: R257306013**

**Discrepancy ID:** 1747555113

**Site:** P3880\_0342

**Patient:** R4045

**Visit:** IP, WEEK 6

**Visit Date:**

**CRF:** PAGE\_20

**Section:** STATUS REVIEW

**Qualifying Value:** 20

**Field:** If Subject was not compliant, approximat

**Row:** 1

**Value Text:** 14

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please review value

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R266548313**

**Discrepancy ID:** 99097611

**Site:** P3880\_0342

**Patient:** R4045

**Visit:** PCM.2

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Ongoing

**Row:** 1

**Value Text:** CHECKED

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify medication is ongoing. Corresponding AE ended on 10Sep2009.

**Internal Comment:** per subject report medication should read ongoing

**Resolution Type:** Confirmed

**Resolution Text:** Verified. JLM 21Apr2010

**Document #: R266549113**

**Discrepancy ID:** 1747571313                      **Site:** P3880\_0342                      **Patient:** R4045  
**Visit:** PCM.3                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Ongoing                      **Row:** 1  
**Value Text:**  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please complete when source is updated.  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 99100811                      **Site:** P3880\_0342                      **Patient:** R4045  
**Visit:** PCM.3                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Stop Date                      **Row:** 1  
**Value Text:** 20090804  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** There were 2 AEs of Headache. One started and stopped on 28Jul2009 and the other on 04Aug2009. Please verify if Advil was taken only on these days. If so, please split into two medications.  
**Internal Comment:** per subject advil was taken 28Jul2009 through 04Aug2009  
**Resolution Type:** Confirmed  
**Resolution Text:** Verified. JLM 21Apr2010

**Discrepancy ID:** 1747571013                      **Site:** P3880\_0342                      **Patient:** R4045  
**Visit:** PCM.3                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:**                      **Row:**  
**Value Text:**  
**Type:** MANUAL HEADER                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please add frequency  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R266549913**

**Discrepancy ID:** 99100911

**Site:** P3880\_0342

**Patient:** R4045

**Visit:** PCM.4

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Drug name

**Row:** 1

**Value Text:** CIMIFIN

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify this is the correct spelling of this medication.

**Internal Comment:** confirmed as per subject

**Resolution Type:** Confirmed

**Resolution Text:** Verified. JLM 21Apr2010



**Document #: R288108013**

**Discrepancy ID:** 73823811

**Site:** P3880\_0342

**Patient:** R4045

**Visit:** AE.3

**Visit Date:**

**CRF:** PAGE\_40

**Section:** AE

**Qualifying Value:** 40

**Field:** Severity

**Row:** 1

**Value Text:**

**Type:** UNIVARIATE

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Value for Severity has not been supplied

**Internal Comment:** severity unknown

**Resolution Type:** Confirmed

**Resolution Text:**

# Deleted CRFs Report