

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 11:54:09

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4096

Ending patient: R4096

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

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

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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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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	Ethnicity
<input type="text" value="26-JUN-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other		<input type="text"/>

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="64.3"/>

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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	119
Diastolic Blood Pressure	MMHG	67
Heart Rate	BEATS/MINUTE	49
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.8
Weight	LB	141.8

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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: 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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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="26-JUN-2009"/>	<input type="text" value="10:52"/>
	<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

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	CONTACT DERMATITIS	23-JUN-2009	08-JAN-2010	<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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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="17"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="13"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="5"/>	COLD TURKEY

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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

Date	Procedure	Findings*	Findings
26-JUN-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
26-JUN-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
26-JUN-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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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

Date	Parameter	Result	Comments
26-JUN-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
26-JUN-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
08-JUL-2009	11:59	5	1.4	

Behavioral Counseling

Date	Parameter	Result	Comments
08-JUL-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="4"/> logs
1.0 g of snus or matching placebo	<input type="text" value="2"/> logs

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="20-JUL-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="63"/>	<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="27-JUL-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="49"/>	<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="30-JUL-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="49"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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

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	116
Diastolic Blood Pressure	MMHG	74
Heart Rate	BEATS/MINUTE	56
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	37.3
Weight	LB	139.2

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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
19-AUG-2009	11:05	7	1.7	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire MNWS Was Questionnaire Administered? 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="1"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="19-AUG-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?
<input type="text" value="19-AUG-2009"/>	<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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="02-SEP-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="28"/>	<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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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	120
Diastolic Blood Pressure	MMHG	61
Heart Rate	BEATS/MINUTE	49
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.0
Weight	LB	139.6

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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-SEP-2009	09:19	8	1.9	

Behavioral Counseling

Date	Parameter	Result	Comments
16-SEP-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

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 logs

1.0 g of snus or matching placebo logs

Status Review

Date

Parameter

Result

Comments

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Was Subject compliant?

Yes No

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

Was Subject asked HDYF? question?

Yes No

Diary Distribution

Date

Did subject receive diary and usage instructions?

Yes No

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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="09-OCT-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="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"/>
	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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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	71
Heart Rate	BEATS/MINUTE	85
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.8
Weight	LB	143.8

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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
28-OCT-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
28-OCT-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
28-OCT-2009	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.

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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
28-OCT-2009	10:26	11	2.3	

Behavioral Counseling

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

Questionnaires

Date

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

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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="28-OCT-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="70"/>	<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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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 type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date Scheduled Timepoint

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

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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	112
Diastolic Blood Pressure	MMHG	79
Heart Rate	BEATS/MINUTE	87
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	37.2
Weight	LB	145.8

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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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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="23-FEB-2010"/>	<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="23-FEB-2010"/>	<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="23-FEB-2010"/>	<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.

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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
23-FEB-2010	13:58	12	2.5	

Behavioral Counseling

Date	Parameter	Result	Comments
23-FEB-2010	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="23-FEB-2010"/>	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="63"/>	<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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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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Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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Previous and Concomitant Medications

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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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Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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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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Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

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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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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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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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Swedish Match AB

Protocol Number: SM 08-01

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Subject Initials

Visit Name

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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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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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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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Document Number

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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

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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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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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](#)

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

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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

Verified Approved Locked Frozen

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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

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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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

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](#)

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 #: R271515713

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Screening	Page_05 05

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Bm	Page number	5	Screening

Group #	Group Name
1	BM

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	27-OCT-1983 26-JUN-2009	03-MAR-2010 14:16:44 Kim Freschly	Data Entry Error

Document #: R296689313

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Onset 1	23-JUN-2009 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
Date of Onset 1	23-JUN-2009	26-APR-2010 13:07:23 Kim Freschly	Row Inserted
Date of Resolution 1	08-JAN-2010 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
Date of Resolution 1	08-JAN-2010	26-APR-2010 13:07:23 Kim Freschly	Row Inserted
Diagnosis/Procedure 1	CONTACT DERMATITIS <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
Diagnosis/Procedure 1	CONTACT DERMATITIS	26-APR-2010 13:07:23 Kim Freschly	Row Inserted
Does the subject have any relevant medication 1	YES NO	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
Does the subject have any relevant medication 1	NO YES	26-APR-2010 13:07:23 Kim Freschly	Data Entry Error
Ongoing 1	<Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
Ongoing 1		26-APR-2010 13:07:23 Kim Freschly	Row Inserted
Sequence Number 1	1 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
Sequence Number 1	1	26-APR-2010 13:07:23 Kim Freschly	Row Inserted
Date of Onset 2	26-JUL-2009 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error

Document #: R296689313

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Date of Resolution 2	03-AUG-2009 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Diagnosis/Procedure 2	VIRAL UPPER RESPIRATORY INFECTION <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Ongoing 2	<Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Sequence Number 2	2 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Date of Onset 3	19-AUG-2009 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Date of Resolution 3	02-SEP-2009 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Diagnosis/Procedure 3	NEURALGIA <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Ongoing 3	<Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Sequence Number 3	3 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Date of Onset 4	21-JUL-2009 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Date of Resolution 4	23-JUL-2009 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Diagnosis/Procedure 4	ANKLE SPRAIN <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Ongoing 4	<Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Sequence Number 4	4 <Row Deleted>	11-MAR-2010 14:00:31 Kim Freschly	Data Entry Error
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Document #: R271516613

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Screening	Page_10 10

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If yes, how many (other attempts to quit (6) 1	5	11-MAR-2010 13:56:44 Kim Freschly	Data Entry Error

Document #: R271518313

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	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 On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	49	03-MAR-2010 14:21:47 Kim Freschly	Data Entry Error

Document #: R296690113

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Ip, Week 13	Page_25 25

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	25	Ip, Week 13

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	10 70	15-MAR-2010 09:42:00 Lana Glaser	Data Entry Error

Document #: R296691013

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Fu, Week 20 & 24	Page_32 32

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	16-MAR-2010 12:02:08 Lana Glaser	Data Entry Error

Document #: R271518513

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm	Page_39 39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Indication 1	BIRTH CONTROL CONTRACEPTION	25-SEP-2009 09:16:37 Kim Freschly	Data Entry Error

Document #: R271518813

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	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
Indication 1	SKIN RASH CONTACT DERMATITIS	15-MAR-2010 09:46:12 Lana Glaser	Data Entry Error

Document #: R271518913

Patient Site	Visit Visit Date	CRF CRF Page
R4096 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

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
Indication 1	NASAL CONGESTION INFLUENZA	15-MAR-2010 09:46:47 Lana Glaser	Data Entry Error

Document #: R271519113

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	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
Indication 1	HEAD COLD INFLUENZA	15-MAR-2010 09:48:14 Lana Glaser	Data Entry Error

Document #: R271519213

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm.5	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.5

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Indication 1	NASAL CONGESTION INFLUENZA	15-MAR-2010 09:48:36 Lana Glaser	Data Entry Error

Document #: R271519313

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	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
Indication 1	NASAL CONGESTION INFLUENZA	16-MAR-2010 11:13:59 Lana Glaser	Data Entry Error

Document #: R271519513

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm.7	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.7

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Indication 1	SKIN RASH CONTACT DERMATITIS	16-MAR-2010 11:14:45 Lana Glaser	Data Entry Error

Document #: R271519713

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm.8	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.8

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	N	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC1 Text 1	NERVOUS SYSTEM, N	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Code 1	N02	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Text 1	ANALGESICS, N02	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Code 1	N02B	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02B	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Code 1	N02BG	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02BG	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	GADATENIN GABAPENTIN	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	GADATENIN GABAPENTIN	14-APR-2010 09:10:08 Lana Glaser	Data Entry Error
Frequency 1	OTHER EVERY DAY	13-APR-2010 10:40:42 Lana Glaser	Data Entry Error
Indication 1	PAIN-MEDIAN NERVE NEURALGIA LOWER EXTREMITIES	16-MAR-2010 11:15:21 Lana Glaser	Data Entry Error
Indication 1	NEURALGIA LOWER EXTREMITIES NEURALGIA UPPER EXTREMITIES	13-APR-2010 10:35:49 Lana Glaser	Data Entry Error
Preferred Term 1	GABAPENTIN	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R271519713

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm.8	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.8

Group #	Group Name
1	CM1

Preferred Term Code 1	01003001001	20-APR-2010 11:39:56	Data Change Carol Kraucyk
Stop Date 1	02-SEP-2009 25-AUG-2009	13-APR-2010 10:40:42	Data Entry Error Lana Glaser
other, specify (frequency) 1	QD X 7 DAYS; TID X 3 WEEKS	14-APR-2010 09:09:48	Data Entry Error Lana Glaser

Document #: R271520513

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm.9	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.9

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	D M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	D11 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	OTHER DERMATOLOGICAL PREPARATIONS, D11 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	D11A M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER DERMATOLOGICAL PREPARATIONS, D11A ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	D11AX M01AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER DERMATOLOGICALS, D11AX ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, M01AB	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Indication 1	PAIN NEURALGIA UPPER EXTREMITIES	14-APR-2010 09:06:43 Lana Glaser	Data Entry Error

Document #: R271521513

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm.10	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.10

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	G M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	GENITO URINARY SYSTEM AND SEX HORMONES, G MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	G02 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	OTHER GYNECOLOGICALS, G02 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	G02C M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER GYNECOLOGICALS, G02C ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STEROIDS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	G02CC M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	ANTIINFLAMMATORY PRODUCTS FOR VAGINAL ADMINISTRAT., G02CC PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Stop Date 1	20-AUG-2009 23-JUL-2009	16-MAR-2010 11:17:22 Lana Glaser	Data Entry Error

Document #: R302427813

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Pcm.11	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.11

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	N	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC1 Text 1	NERVOUS SYSTEM, N	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Code 1	N02	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Text 1	ANALGESICS, N02	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Code 1	N02B	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02B	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC4 Code 1	N02BG	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC4 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02BG	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug Modified Reported Term 1	GAVAPENTIN GABAPENTIN	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug name 1	GADATENIN GAVAPENTIN	14-APR-2010 09:10:55 Lana Glaser	Data Entry Error
Drug name 1	GAVAPENTIN GABAPENTIN	26-APR-2010 12:18:13 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 26Apr2010
Preferred Term 1	GABAPENTIN	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Preferred Term Code 1	01003001001	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change

Document #: R296691913

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Ae	Page_40 40

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	26-APR-2010 08:08:18 Lana Glaser	Data Entry Error

Document #: R296692213

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Ae.1	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.1

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Taken 1	OTHER DRUG	11-MAR-2010 14:04:30 Kim Freschly	Pass1

Document #: R296692313

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Ae.2	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.2

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Adverse Event 1	VIRAL UPPER RESPIRATORY INFECTION INFLUENZA		11-MAR-2010 14:04:50 Kim Freschly	Investigator Correction
Serious Event 1	NO		03-MAR-2010 14:39:43 Kim Freschly	Data Entry Error

Document #: R296692413

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Ae.3	Page_40

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ae	Page number	40	Ae.3

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1	WARM COMPRESS	03-MAR-2010 14:42:06 Kim Freschly	Data Entry Error
Action Taken 1	OTHER TREATMENT OTHER DRUG	03-MAR-2010 14:42:06 Kim Freschly	Data Entry Error

Document #: R296693413

Patient Site	Visit Visit Date	CRF CRF Page
R4096 P3880_0342	Study Competition	Page_46 46

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ds	Page number	46	Study Competition

Group #	Group Name
1	DS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Other specify (2) 1	SUBJECT COMPLETED BUT OUTSIDE THE WINDOW	24-MAR-2010 09:35:43 Lana Glaser	Data Entry Error
Reason for withdrawal 1	NA OTHER	24-MAR-2010 09:35:43 Lana Glaser	Data Entry Error

Discrepancy Detail Report

Document #: R271515713

Discrepancy ID: 19342411

Site: P3880_0342

Patient: R4096

Visit: SCREENING

Visit Date:

CRF: PAGE_05

Section: BM

Qualifying Value: 5

Field: Date

Row: 1

Value Text: 20090626

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R271515913

Discrepancy ID: 1760110713

Site: P3880_0342

Patient: R4096

Visit: SCREENING

Visit Date:

CRF: PAGE_06

Section: VS

Qualifying Value: 6

Field: Heart Rate

Row: 1

Value Text: 49

Type: UNIVARIATE

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Value of 49 for Heart Rate below expected minimum of 50

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R271516613

Discrepancy ID: 19342711 **Site:** P3880_0342 **Patient:** R4096
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: 5
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please complete when available.
Internal Comment: Source indicates "numerous times". Please clarify.
Resolution Type: Confirmed
Resolution Text:

Document #: R296689313

Discrepancy ID: 111915611

Site: P3880_0342

Patient: R4096

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Date

Row: 1

Value Text: 20090626

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Contact Dermatitis was removed as AE due to being prior to randomization. Please verify if it should be added to MH.

Internal Comment: added per PI

Resolution Type: Confirmed

Resolution Text: Verified. JLM 26Apr2010

Document #: R271518013

Discrepancy ID: 1760149613 **Site:** P3880_0342 **Patient:** R4096
Visit: IP, WEEK 10 **Visit Date:**
CRF: PAGE_22 **Section:** VS **Qualifying Value:** 22
Field: Heart Rate **Row:** 1
Value Text: 49
Type: UNIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Value of 49 for Heart Rate below expected minimum of 50
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R296690113

Discrepancy ID: 84269011

Site: P3880_0342

Patient: R4096

Visit: IP, WEEK 13

Visit Date:

CRF: PAGE_25

Section: STATUS REVIEW

Qualifying Value: 25

Field: If Subject was not compliant, approximat

Row: 1

Value Text: 70

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify 70 should be entered per source.

Internal Comment:

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

Resolution Text:

Document #: R271518813

Discrepancy ID: 84273111

Site: P3880_0342

Patient: R4096

Visit: PCM.2

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: CONTACT DERMATITIS

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify should be "contact dermititis".

Internal Comment:

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

Resolution Text:

Document #: R271518913

Discrepancy ID: 84412311

Site: P3880_0342

Patient: R4096

Visit: PCM.3

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: INFLUENZA

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify per source indication has been updated to influenza.

Internal Comment:

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

Resolution Text:

Document #: R271519113

Discrepancy ID: 84412411

Site: P3880_0342

Patient: R4096

Visit: PCM.4

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: INFLUENZA

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify per source indication has been updated to influenza.

Internal Comment:

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

Resolution Text:

Document #: R271519213

Discrepancy ID: 84412511

Site: P3880_0342

Patient: R4096

Visit: PCM.5

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: INFLUENZA

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify per source indication has been updated to influenza.

Internal Comment:

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

Resolution Text:

Document #: R271519313

Discrepancy ID: 85477211 **Site:** P3880_0342 **Patient:** R4096
Visit: PCM.6 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: INFLUENZA
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update per additional source information (Influenza)
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R271519513

Discrepancy ID: 85477311

Site: P3880_0342

Patient: R4096

Visit: PCM.7

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: CONTACT DERMATITIS

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please match Ae verbatim - contact dermatitis

Internal Comment:

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

Resolution Text:

Document #: R271519713

Discrepancy ID: 99120711 **Site:** P3880_0342 **Patient:** R4096
Visit: PCM.8 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Drug name **Row:** 1
Value Text: GABAPENTIN
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify drug name/spelling.

Internal Comment:

Resolution Type: Confirmed
Resolution Text: Verified. JLM 21Apr2010

Discrepancy ID: 85478511 **Site:** P3880_0342 **Patient:** R4096
Visit: PCM.8 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: NEURALGIA UPPER EXTREMITIES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please match AE verbatim - neurologic UE

Internal Comment:

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

Discrepancy ID: 99117711 **Site:** P3880_0342 **Patient:** R4096
Visit: PCM.8 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: other, specify (frequency) **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Each separate frequency will need to be captured as a separate medication. Please split medication.

Internal Comment:

Resolution Type: Confirmed
Resolution Text: Verified. JLM 21Apr2010

R271519713

Discrepancy ID: 99117411

Site: P3880_0342

Patient: R4096

Visit: PCM.8

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: AE states Neurologia UPPER extremities. Please reconcile.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R271520513

Discrepancy ID: 99120811

Site: P3880_0342

Patient: R4096

Visit: PCM.9

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: NEURALGIA UPPER EXTREMITIES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: There is not corresponding AE of 'Pain.' Please reconcile.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R271521513

Discrepancy ID: 85479011

Site: P3880_0342

Patient: R4096

Visit: PCM.10

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Stop Date

Row: 1

Value Text: 20090723

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please clarify stop date as related AE resolved on 23Jul09

Internal Comment:

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

Resolution Text:

Document #: R296692213

Discrepancy ID: 85480111

Site: P3880_0342

Patient: R4096

Visit: AE.1

Visit Date:

CRF: PAGE_40

Section: AE

Qualifying Value: 40

Field: Resolved Date

Row: 1

Value Text: 20090723

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review stop date as ConMed was continued until 20Aug09

Internal Comment: per source, correct as entered

Resolution Type: Confirmed

Resolution Text:

Document #: R296693413

Discrepancy ID: 89282611

Site: P3880_0342

Patient: R4096

Visit: STUDY COMPETITION **Visit Date:**

CRF: PAGE_46

Section: DS

Qualifying Value: 46

Field: Reason for withdrawal

Row: 1

Value Text: OTHER

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify Week 28/Completion dates. If correct, Week 28 assessments occurred outside of the +/- 7 day window of the scheduled visit date. Please update Study Completion Status to Other, specify. Specification should be: Subject completed but was out of window.

Internal Comment: corrected

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

Resolution Text:

Deleted CRFs Report