

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 08:32:50

Report Parameters

Site: P3880_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4010

Ending patient: R4010

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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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

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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-FEB-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="66.6"/>

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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

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	127
Diastolic Blood Pressure	MMHG	82
Heart Rate	BEATS/MINUTE	81
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	37.0
Weight	LB	126.0

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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="26-FEB-2009"/>	<input type="text" value="11:14"/>
	<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

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	HYPERTENSION	00-00-2000		<input checked="" type="checkbox"/> Ongoing
2	POSTMENOPAUSAL HORMONE REPLACEMENT TH	00-00-2000		<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

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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OverFlow Section For Document Number R275319813

1 POSTMENOPAUSAL HORMONE REPLACEMENT THERAPY

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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

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="15"/>	
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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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-FEB-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
26-FEB-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
26-FEB-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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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

Date	Parameter	Result	Comments
26-FEB-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
26-FEB-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
11-MAR-2009	09:49	20	3.8	

Behavioral Counseling

Date	Parameter	Result	Comments
11-MAR-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 logs
1.0 g of snus or matching placebo 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

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="18-MAR-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="98"/>	<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="25-MAR-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="01-APR-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="35"/>	<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
<input type="text" value="08-APR-2009"/>	<input type="text" value="WEEK 4"/>	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="35"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

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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	80
Heart Rate	BEATS/MINUTE	74
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.8
Weight	LB	125.4

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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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
22-APR-2009	07:22	4	1.2	

Behavioral Counseling

Date	Parameter	Result	Comments
22-APR-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="2"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="22-APR-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="35"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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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

Status Review

Date	Parameter	Result	Comments
06-MAY-2009	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="35"/>	
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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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	129
Diastolic Blood Pressure	MMHG	85
Heart Rate	BEATS/MINUTE	70
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.6
Weight	LB	127.8

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Page Version No. PAGE_22 (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

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
20-MAY-2009	08:03	0	0.0	

Behavioral Counseling

Date	Parameter	Result	Comments
20-MAY-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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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="10-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="35"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	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	128
Diastolic Blood Pressure	MMHG	85
Heart Rate	BEATS/MINUTE	65
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.0
Weight	LB	124.6

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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
07-JUL-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
07-JUL-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	<input type="text"/>
07-JUL-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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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
07-JUL-2009	08:18	6	1.5	

Behavioral Counseling

Date	Parameter	Result	Comments
07-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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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
07-JUL-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="35"/>	
	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="35"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="35"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE_32 (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

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	125
Diastolic Blood Pressure	MMHG	86
Heart Rate	BEATS/MINUTE	85
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.8
Weight	LB	ND

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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: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_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-SEP-2009	08:56	15	3.0	

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

Page Version No. PAGE_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-SEP-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="49"/>	<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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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

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

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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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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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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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 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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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

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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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

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.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

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

Comments

Date Actual Time

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

Comments

Verified Approved Locked Frozen

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

Document Number

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 #: R275319813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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
Diagnosis/Procedure 2	POSTMENOPAUSAL HRT POSTMENOPAUSAL HORMONE REPLACEMENT THERAPY	18-MAR-2010 08:31:58 Lana Glaser	Data Entry Error

Document #: R240106613

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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
Comments (other attempts) (7) 1	COLD TURKEY	10-JUN-2009 12:01:43 Kim Freschly	Data Entry Error
If yes, how many (other attempts to quit) (6) 1	4 1	04-JAN-2010 10:00:22 Kim Freschly	Data Entry Error

Document #: R240108813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Screening	Page_11 11

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

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings* 3	NO NE	13-MAY-2009 11:29:23 Kim Freschly	Data Entry Error
Findings* 3	NE NO	10-JUN-2009 12:02:31 Kim Freschly	Data Entry Error

Document #: R275321413

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Screening	Page_12 12

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	NO YES	08-JAN-2010 10:04:35 Kim Freschly	Data Entry Error
Findings 1	UPPER DENTURES	08-JAN-2010 10:05:00 Kim Freschly	Row Inserted
Sequence Number 1	1	08-JAN-2010 10:05:00 Kim Freschly	Row Inserted

Document #: R243267813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	23-APR-2009 10:42:15 Kim Freschly	Data Entry Error
DCI Blank Flag 1	Y N	23-APR-2009 10:42:27 Kim Freschly	Data Entry Error

Document #: R243267813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (10) 1	98	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (behavioral counseling) (6) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (contacted by phone) (1) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (how many cigarettes) (5) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (smoking status reviewed) (2) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (study product reviewed) (3) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Date 1	18-MAR-2009	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Scheduled Timepoint 1	WEEK 1	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Was Subject contacted by telephone (1) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted

Document #: R243267813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Was Subject's smoking status reviewed (2) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
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Was Subject's use of study product review (3) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
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Document #: R243267813

Patient Site	Visit Visit Date	CRF CRF Page	
R4010 P3880_0342	Sptp, Weeks 1-4	Page_16 16	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16.1	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (11) 1	70	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (behavioral counseling) (6) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (contacted by phone) (1) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (how many cigarettes) (5) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (smoking status reviewed) (2) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (study product reviewed) (3) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Date 1	25-MAR-2009	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Scheduled Timepoint 1	WEEK 2	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Was Subject contacted by telephone (1) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted

Document #: R243267813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16.1	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Was Subject's smoking status reviewed (2) 1	YES	23-APR-2009 10:42:27	Row Inserted Kim Freschly
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Was Subject's use of study product review (3) 1	YES	23-APR-2009 10:42:27	Row Inserted Kim Freschly
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Document #: R243267813

Patient Site	Visit Visit Date	CRF CRF Page	
R4010 P3880_0342	Sptp, Weeks 1-4	Page_16 16	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16A	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (10) 1	35	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (behavioral counseling) (6) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (contacted by phone) (1) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (how many cigarettes) (5) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (smoking status reviewed) (2) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Comments (study product reviewed) (3) 1		23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Date 1	01-APR-2009	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Scheduled Timepoint 1	WEEK 3	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
Was Subject contacted by telephone (1) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted

Document #: R243267813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Sptp, Weeks 1-4	Page_16 16

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	16A	Sptp, Weeks 1-4

Group #	Group Name
1	CHKYN

Was Subject's smoking status reviewed (2) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
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Was Subject's use of study product review (3) 1	YES	23-APR-2009 10:42:27 Kim Freschly	Row Inserted
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Document #: R251870313

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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	1 14	11-SEP-2009 13:39:11 Kim Freschly	Investigator Correction

Document #: R275323813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Fu, Week 20 & 24	Page_32 32

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32	Fu, Week 20 & 24

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	35	11-JAN-2010 09:02:00 Kim Freschly	Data Entry Error
If Subject was not compliant, approximat (5) 1	35	11-JAN-2010 09:03:15 Kim Freschly	Data Entry Error
Was Subject compliant (4) 1	YES NO	04-JAN-2010 10:01:24 Kim Freschly	Data Entry Error
Was Subject compliant (4) 1	NO	11-JAN-2010 09:01:46 Kim Freschly	Data Entry Error
Was Subject compliant (4) 1	NO	11-JAN-2010 09:03:15 Kim Freschly	Data Entry Error

Document #: R275323913

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Fu, Week 28	Page_33 33

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	33	Fu, Week 28

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	26-AUG-2009 23-SEP-2009	22-OCT-2009 11:34:37 Kim Freschly	Data Entry Error

Document #: R240111713

Patient Site	Visit Visit Date	CRF CRF Page
R4010 P3880_0342	Pcm.1	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.1

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Indication 1	HRT HORMONE REPLACEMENT THERAPY	13-APR-2010 08:30:15 Lana Glaser	Data Entry Error

Document #: R240113013

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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
ATC1 Code 1	N	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	NERVOUS SYSTEM, N	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	N02	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	ANALGESICS, N02	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Code 1	N02B	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	OTHER ANALGESICS AND ANTIPYRETICS, N02B	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	N02BE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	ANILIDES, N02BE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term 1	PARACETAMOL	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	00020001001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name 1	TYLENOL /00020001/	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name Code 1	00020001005	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

Document #: R275324913

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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	LEFT SHOULDER PAIN ARTHRALGIA LEFT SHOULDER	22-OCT-2009 11:53:07 Kim Freschly	Data Entry Error

Document #: R275325113

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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	Data Change
ATC1 Text 1	DERMATOLOGICALS, D SYSTEMIC HORMONAL PREP., EXCL. SEX HORM. AND INSULIN, H	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	D07 H02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, D07 CORTICOSTEROIDS FOR SYSTEMIC USE, H02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	D07A H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	CORTICOSTEROIDS, PLAIN, D07A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, H02A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	D07AA H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	CORTICOSTEROIDS, WEAK (GROUP I), D07AA GLUCOCORTICIDS, H02AB	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
Drug Modified Reported Term 1	DEPOMEDROL DEPO MEDROL	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	DEPOMEDROL DEPO MEDROL	12-APR-2010 10:11:22 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 12Apr2010
Indication 1	LEFT SHOULDER PAIN ARTHRALGIA LEFT SHOULDER	22-OCT-2009 11:53:16 Kim Freschly	Data Entry Error
Start Date 1	19-MAR-2009 19-MAY-2009	06-JAN-2010 09:47:01 Lana Glaser	Data Entry Error

Document #: R275325113

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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

Stop Date	19-MAR-2009	06-JAN-2010 09:47:01	Data Entry Error
1	29-JUL-2009	Lana Glaser	
Stop Date	29-JUL-2009	08-JAN-2010 10:05:57	Data Entry Error
1	19-MAY-2009	Kim Freschly	
Trade Name	DEPOMEDROL	20-APR-2010 11:39:56	Data Change
1	DEPO MEDROL	Carol Kraucyk	
Trade Name Code	00049603030	20-APR-2010 11:39:56	Data Change
1	00049603013	Carol Kraucyk	

Document #: R275329813

Patient Site	Visit Visit Date	CRF CRF Page
R4010 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
Resolved Date 1	20-MAY-2009 20-AUG-2009	06-JAN-2010 09:54:47 Lana Glaser	Data Entry Error

Document #: R240106613

Discrepancy ID: 1781341913

Site: P3880_0342

Patient: R4010

Visit: SCREENING

Visit Date:

CRF: PAGE_10

Section: SMOKING HISTORY

Qualifying Value: 10

Field: If yes, how many (other attempts to quit

Row: 1

Value Text: 1

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per smoking Hx clarification form subject only attempted to quit 2 times.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R240108813

Discrepancy ID: 1672660813

Site: P3880_0342

Patient: R4010

Visit: SCREENING

Visit Date:

CRF: PAGE_11

Section: ORAL HEALTH EXA

Qualifying Value: 11

Field: Findings*

Row: 3

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please update to 'No' per CRF guidelines

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R275319813

Discrepancy ID: 1781341513

Site: P3880_0342

Patient: R4010

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Diagnosis/Procedure

Row: 2

Value Text: POSTMENOPAUSAL HORMONE REPLACEMENT THERAPY

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please update to full text rather than abbreviation (HRT).

Internal Comment: corrected

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

Resolution Text:

Document #: R275321413

Discrepancy ID: 36161811

Site: P3880_0342

Patient: R4010

Visit: SCREENING

Visit Date:

CRF: PAGE_12

Section: PE

Qualifying Value: 12

Field: Does the subject have any abnormal findi

Row: 1

Value Text: YES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please add PE findings

Internal Comment: Upper dentures

Resolution Type: Confirmed

Resolution Text:

Document #: R251870313

Discrepancy ID: 1690569413

Site: P3880_0342

Patient: R4010

Visit: IP, WEEK 10

Visit Date:

CRF: PAGE_24

Section: STATUS REVIEW

Qualifying Value: 24

Field: If Subject was not compliant, approximat

Row: 1

Value Text: 14

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please use value from week 10 diary

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R275323813

Discrepancy ID: 1781344113 **Site:** P3880_0342 **Patient:** R4010
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32
Field: Was Subject compliant **Row:** 1
Value Text: NO
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review compliance response
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R240111713

Discrepancy ID: 98968711 **Site:** P3880_0342 **Patient:** R4010
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: HORMONE REPLACEMENT THERAPY
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please provide full indication for clarity (Hormone Replacement Therapy)
Internal Comment:
Resolution Type: Confirmed
Resolution Text: Verified. JLM 20Apr2010

Document #: R240113013

Discrepancy ID: 98968811

Site: P3880_0342

Patient: R4010

Visit: PCM.4

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: STRESS HEADACHE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Stress headache is not captured as medical history. Please verify adding.

Internal Comment: per Dr. Stoltz subject's history of stress headache is not relevant to study

Resolution Type: Confirmed

Resolution Text: Verified. JLM 21Apr2010

Document #: R275325113

Discrepancy ID: 1781401913

Site: P3880_0342

Patient: R4010

Visit: PCM.7

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Stop Date

Row: 1

Value Text: 20090519

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review stop date to footnote 3.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R275329813

Discrepancy ID: 1781457513 **Site:** P3880_0342 **Patient:** R4010
Visit: AE.3 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Action Taken **Row:** 1
Value Text: OTHER DRUG
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Source does not match CRF.
Internal Comment: Pls have SM update source AE - action taken - check conmed box
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1781457913 **Site:** P3880_0342 **Patient:** R4010
Visit: AE.3 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Adverse Event **Row:** 1
Value Text: COUGH
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review if AE for headache (per conmed source) should be documented and added to the CRF per protocol (all AEs from screening on will be captured)
Internal Comment: AE of viral syndrome added
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1781457413 **Site:** P3880_0342 **Patient:** R4010
Visit: AE.3 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: Resolved Date **Row:** 1
Value Text: 20090820
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review date
Internal Comment: date corrected
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R286632413

Discrepancy ID: 35285111 **Site:** P3880_0342 **Patient:** R4010
Visit: AE.4 **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: per source, severity not captured
Resolution Type: Confirmed
Resolution Text:

Discrepancy ID: 39638811 **Site:** P3880_0342 **Patient:** R4010
Visit: AE.4 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Resolved Date and Time is missing and Ongoing is null for Adverse Event <VIRAL SYNDROME>.
Please either provide resolved date and time OR check Ongoing.
Internal Comment:
Resolution Type: No Action Required
Resolution Text: Check firing due to UNK time. No action needed. KAY 02Feb2010.

Discrepancy ID: 39640611 **Site:** P3880_0342 **Patient:** R4010
Visit: AE.4 **Visit Date:**
CRF: PAGE_40 **Section:** AE **Qualifying Value:** 40
Field: **Row:**
Value Text:
Type: MULTIVARIATE **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Outcome to Date is equal to RECOVERED for VIRAL SYNDROME but Resolved Date and/or Time
are missing. Please reconcile.
Internal Comment:
Resolution Type: No Action Required
Resolution Text: Check firing due to UNK time. No action needed. KAY 02Feb2010.

Deleted CRFs Report