

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 16:13:26

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5017

Ending patient: R5017

Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	Abc 123

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

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

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

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

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Inclusion Criteria

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

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

* If No, document on Subject Eligibility Page.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Exclusion Criteria

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

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

* If Yes, document on Subject Eligibility Page.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="13-JUL-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 type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input checked="" 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="062.0"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	124
Diastolic Blood Pressure	MMHG	85
Heart Rate	BEATS/MINUTE	56
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.0
Weight	LB	215.8

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

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

Urine Drug Screen

Drug Screen Result*

Positive Negative

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="13-JUL-2009"/>	<input type="text" value="10:21"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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	IRREGULAR HEART BEAT	00-00-1970		<input checked="" type="checkbox"/> Ongoing
2	HOT FLASHES	00-00-2003		<input checked="" type="checkbox"/> Ongoing
3	TOTAL HYSTERECTOMY	00-00-2003	00-00-2003	<input type="checkbox"/> Ongoing
4	OCCASIONAL HEADACHES	00-00-1980		<input checked="" type="checkbox"/> Ongoing
5	ALLERGIC TO POISON IVY	05-JUL-2009		<input checked="" type="checkbox"/> Ongoing
6	CHRONIC FLATULENCE	00-00-2008		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="51"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="10"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="4"/>	NICOTINE GUM - TWICE; NICODERM PATCH - TWICE
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 ONCE
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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	

Verified Approved Locked Frozen

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

Document Number

OverFlow Section For Document Number R259026013

1 NICOTINE GUM - TWICE; NICODERM PATCH - TWICE

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Behavioral Counseling

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
17-JUL-2009	10:19	27	4.9	

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time
Was Subject randomized? Yes No

Product Dispensation

Date

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

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

Document Number

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="27-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="56"/>	<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="04-AUG-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="56"/>	<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="10-AUG-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="56"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

Questionnaire MNWS Was Questionnaire Administered? Yes No

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="14-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="42"/>	<input type="text"/>
	Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Product Dispensation

Date

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

Status Review

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text"/>	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's use of study product reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	<input type="text"/>
	Was 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"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	117
Diastolic Blood Pressure	MMHG	85
Heart Rate	BEATS/MINUTE	61
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	37.0
Weight	LB	206.8

Verified Approved Locked Frozen

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.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
21-DEC-2009	09:52	18	3.5	

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="21-DEC-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="28"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

Verified Approved Locked Frozen

Page Version No. PAGE_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"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_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
<input type="text"/>				

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

Page Version No. PAGE_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"/>	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 Subject asked HDYF? question?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time

Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

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

Action Taken: Select only one

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

Outcome to Date Select only one

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

Date	Requisition Number	Clinically Significant?	Test Name CS Labs Only	Test Code ID CS Labs Only	Comments
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

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

Comments

Date Actual Time

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

Comments

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

Verified Approved Locked Frozen

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

Document Number

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 #: **R259022013**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Screening	Page_07 07

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

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	25-FEB-2010 12:34:09 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	25-FEB-2010 12:34:58 Sharon Ladenes	Data Entry Error

Document #: **R259022013**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Screening	Page_07 07

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	13-JUL-2009	25-FEB-2010 12:34:58 Sharon Ladenes	Row Inserted
No (Specify samples not done, reason)/Co 1		25-FEB-2010 12:34:58 Sharon Ladenes	Row Inserted
Requisition Number 1: (1) 1	197-967-0027-0	25-FEB-2010 12:34:58 Sharon Ladenes	Row Inserted
Requisition Number 1: (1) 1	197-967-0027-0 194-967-0027-0	31-MAR-2010 12:12:19 Sharon Ladenes	Data Entry Error
Requisition Number 2 (if applicable): (2) 1		25-FEB-2010 12:34:58 Sharon Ladenes	Row Inserted
Requisition Number 3 (if applicable): (3) 1		25-FEB-2010 12:34:58 Sharon Ladenes	Row Inserted
Were the scheduled laboratory samples ob 1	YES	25-FEB-2010 12:34:58 Sharon Ladenes	Row Inserted
Were there any clinically significant la (1) 1	NO	25-FEB-2010 12:34:58 Sharon Ladenes	Row Inserted

Document #: **R259023113**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Onset 3	00-00-2004 <Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Date of Onset 3	00-00-2003	22-OCT-2009 14:49:46 Sharon Ladenes	Row Inserted
Date of Resolution 3	00-00-2005 <Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Date of Resolution 3	00-00-2003	22-OCT-2009 14:49:46 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 3	LUMPECTOMY <Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 3	BILATERAL OOPHORECTOMY	22-OCT-2009 14:49:46 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 3	BILATERAL OOPHORECTOMY TOTAL HYSTERECTOMY	10-FEB-2010 11:36:22 Sharon Ladenes	Data Entry Error
Ongoing 3	<Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Ongoing 3		22-OCT-2009 14:49:46 Sharon Ladenes	Row Inserted
Sequence Number 3	3 <Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Sequence Number 3	3	22-OCT-2009 14:49:46 Sharon Ladenes	Row Inserted
Date of Onset 5	00-00-2003 <Row Deleted>	04-DEC-2009 13:34:47 Sharon Ladenes	Data Entry Error
Date of Onset 5	05-JUL-2009	13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Date of Resolution 5	00-00-2003 <Row Deleted>	04-DEC-2009 13:34:47 Sharon Ladenes	Data Entry Error

Document #: **R259023113**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Date of Resolution 5		13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 5	FULL HYSTERECTOMY <Row Deleted>	04-DEC-2009 13:34:47 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 5	ALLERGIC TO POISON IVY	13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Ongoing 5	<Row Deleted>	04-DEC-2009 13:34:47 Sharon Ladenes	Data Entry Error
Ongoing 5	CHECKED	13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Sequence Number 5	5 <Row Deleted>	04-DEC-2009 13:34:47 Sharon Ladenes	Data Entry Error
Sequence Number 5	5	13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Date of Onset 6	00-00-2003 <Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Date of Onset 6	00-00-2008	13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Date of Resolution 6	00-00-2003 <Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Date of Resolution 6		13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 6	BILATERAL OOPHORECTOMY <Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 6	FLATULENCE	13-JAN-2010 14:35:48 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 6	FLATULENCE CHRONIC FLATULENCE	04-MAR-2010 13:50:28 Sharon Ladenes	Data Entry Error
Ongoing 6	<Row Deleted>	22-OCT-2009 14:49:46 Sharon Ladenes	Data Entry Error

Document #: **R259023113**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Ongoing		13-JAN-2010 14:35:48	Row Inserted
6	CHECKED	Sharon Ladenes	
Sequence Number	6	22-OCT-2009 14:49:46	Data Entry Error
6	<Row Deleted>	Sharon Ladenes	
Sequence Number		13-JAN-2010 14:35:48	Row Inserted
6	6	Sharon Ladenes	

Document #: R259026013

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Screening	Page_10 10

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (NRT) (4) 1	NICOTINE GUM NICOTINE GUM - TWICE; NICODERM PATCH - TWICE;	12-JAN-2010 16:48:05 Sharon Ladenes	Data Entry Error
Comments (NRT) (4) 1	NICOTINE GUM - TWICE; NICODERM PATCH - TWICE; NICOTINE GUM - TWICE; NICODERM PATCH - TWICE	11-MAR-2010 09:37:47 Kryisia Magnuson	ODM/SEC Removed extra ; KAY 11Mar2010.
Comments (pharmaceuticals) (5) 1	NICOTENE PATCH NICODERM PATCH	10-NOV-2009 11:56:05 Sharon Ladenes	Data Entry Error
Comments (pharmaceuticals) (5) 1	NICODERM PATCH CHANTIX ONCE	12-JAN-2010 16:48:05 Sharon Ladenes	Data Entry Error
If Yes, how many (nicotine replacement) (3) 1	2 4	12-JAN-2010 16:48:05 Sharon Ladenes	Data Entry Error

Document #: **R276758813**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Ip, Week 13	Page_25 25

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	18-JAN-2010 12:12:39 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	19-JAN-2010 12:22:55 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	N Y	15-MAR-2010 17:40:36 Stephanie Felton	Data Entry Error

Document #: **R276758813**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	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
Comments (HDYF) (8) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Comments (behavioral counseling) (6) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Comments (compliant) (4) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Comments (cut down) (9) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Comments (how many cigarettes) (5) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Comments (smoking status reviewed) (2) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Comments (study product reviewed) (3) 1		19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Date 1	26-OCT-2009	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
If Subject was not compliant, approximat (5) 1	21	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted

Document #: **R276758813**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	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

Was Subject asked HDYF? (8) 1	YES	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
----------------------------------	-----	--	--------------

Was Subject compliant (4) 1	NO	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
--------------------------------	----	--	--------------

Was Subject contacted by telephone (1) 1	YES	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
---	-----	--	--------------

Was Subject's smoking status reviewed (2) 1	YES	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
--	-----	--	--------------

Was Subject's use of study product reviewed (3) 1	YES	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
--	-----	--	--------------

Was subject instructed to cut down on pr (9) 1	YES	19-JAN-2010 12:22:55 Sharon Ladenes	Row Inserted
---	-----	--	--------------

Document #: **R285717413**

Patient Site	Visit Visit Date	CRF CRF Page	
R5017 CD_001	Ip, Week 16	Page_28 28	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Oral Health Exam	Page number	28	Ip, Week 16

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings* 3	NE NO	11-JAN-2010 15:15:54 Sharon Ladenes	Data Entry Error

Document #: **R267074713**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Pcm	Page_39 39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
Dose 1	1	05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
Dose 1	1 500	05-OCT-2009 14:00:24 Sharon Ladenes	Data Entry Error
Drug name 1	ADVIL	05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
Frequency 1	EVERY DAY	05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
Frequency 1	EVERY DAY ONCE	10-FEB-2010 11:38:53 Sharon Ladenes	Data Entry Error

Document #: R267074713

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Pcm	Page_39 39

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

Group #	Group Name
1	CM1

Has the subject taken any medications pr 1	NO YES	05-OCT-2009 13:56:49 Sharon Ladenes	Data Entry Error
---	-----------	--	------------------

Indication 1	HEADACHE	05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
-----------------	----------	--	--------------

Ongoing 1		05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
--------------	--	--	--------------

Start Date 1	05-AUG-2005	05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
-----------------	-------------	--	--------------

Start Date 1	05-AUG-2005 05-JUN-200595	05-OCT-2009 14:00:24 Sharon Ladenes	Data Entry Error
-----------------	------------------------------	--	------------------

Start Date 1	05-JUN-200595 05-JUN-2009	05-OCT-2009 14:01:22 Sharon Ladenes	Data Entry Error
-----------------	------------------------------	--	------------------

Start Date 1	05-JUN-2009 05-JUL-2009	13-JAN-2010 14:14:08 Sharon Ladenes	Data Entry Error
-----------------	----------------------------	--	------------------

Stop Date 1	05-JUN-2009	05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
----------------	-------------	--	--------------

Stop Date 1	05-JUN-2009 05-JUL-2009	13-JAN-2010 14:14:08 Sharon Ladenes	Data Entry Error
----------------	----------------------------	--	------------------

Unit 1	TABLET	05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
-----------	--------	--	--------------

Unit 1	TABLET MILLIGRAMS	05-OCT-2009 14:00:24 Sharon Ladenes	Data Entry Error
-----------	----------------------	--	------------------

other, specify (frequency) 1		05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
------------------------------------	--	--	--------------

other, specify (unit) 1		05-OCT-2009 13:56:49 Sharon Ladenes	Row Inserted
-------------------------------	--	--	--------------

Document #: **R272839113**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	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
ATC1 Code 1	D	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC1 Code 1	D R	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC1 Text 1	DERMATOLOGICALS, D	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC1 Text 1	DERMATOLOGICALS, D RESPIRATORY SYSTEM, R	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Code 1	D04	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Code 1	D04 R06	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIPRURITICS, INCL ANTIHIIST, ANESTHET, ETC., D04	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Text 1	ANTIPRURITICS, INCL ANTIHIIST, ANESTHET, ETC., D04 ANTIHIISTAMINES FOR SYSTEMIC USE, R06	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Code 1	D04A	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Code 1	D04A R06A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC3 Text 1	ANTIPRURITICS, INCL ANTIHIIST, ANESTHET, ETC., D04A	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Text 1	ANTIPRURITICS, INCL ANTIHIIST, ANESTHET, ETC., D04A ANTIHIISTAMINES FOR SYSTEMIC USE, R06A	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC4 Code 1	D04AA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change

Document #: R272839113

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Pcm.1	Page_39

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

Group #	Group Name
1	CM1

ATC4 Code 1	D04AA R06AA	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
ATC4 Text 1	ANTI HISTAMINES FOR TOPICAL USE, D04AA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC4 Text 1	ANTI HISTAMINES FOR TOPICAL USE, D04AA AMINOALKYL ETHERS, R06AA	26-APR-2010 14:24:56 Joanne Mccaigue	Class. Change
Drug Modified Reported Term 1	BENEDRYL BENADRYL	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug name 1	BENEDRYL BENADRYL	26-APR-2010 12:20:51 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 26Apr2010
Indication 1	ASTHMA POISON IVY	05-OCT-2009 14:03:08 Sharon Ladenes	Data Entry Error
Preferred Term 1	DIPHENHYDRAMINE HYDROCHLORIDE	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Preferred Term Code 1	00000402001	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Start Date 1	05-JUN-2009 05-JUL-2009	13-JAN-2010 14:30:05 Sharon Ladenes	Data Entry Error
Stop Date 1	06-JUN-2009 06-JUL-2009	13-JAN-2010 14:30:05 Sharon Ladenes	Data Entry Error
Trade Name 1	BENADRYL /00000402/	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Trade Name Code 1	00000402002	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change

Document #: **R272839713**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	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	GAS FLATULENCE	13-JAN-2010 14:30:42 Sharon Ladenes	Data Entry Error
Stop Date 1	05-JUN-2009 05-JUL-2009	13-JAN-2010 14:30:42 Sharon Ladenes	Data Entry Error

Document #: **R272840113**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Pcm.3	Page_39

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

Group #	Group Name
1	CM1

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

Document #: R278886013

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Pcm.4	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Code 1	C03	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Text 1	DIURETICS, C03	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Code 1	C03D	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Text 1	POTASSIUM-SPARING AGENTS, C03D	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Code 1	C03DB	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Text 1	OTHER POTASSIUM-SPARING AGENTS, C03DB	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	TRIAMITERENE TRIAMTERENE	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	TRIAMITERENE TRIAMTERENE	09-APR-2010 16:03:16 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010
Indication 1	ELEVATED BLOOD PRESSUE ELEVATED BLOOD PRESSURE	09-APR-2010 16:03:29 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010
Indication 1	ELEVATED BLOOD PRESSURE HYPERTENSION	21-APR-2010 11:17:37 Sharon Ladenes	Data Entry Error
Preferred Term 1	TRIAMTERENE	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: **R278886013**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Pcm.4	Page_39

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

Group #	Group Name
1	CM1

Preferred Term Code 1	00020201001	20-APR-2010 11:39:56	Data Change Carol Kraucyk
--------------------------	-------------	----------------------	------------------------------

Document #: **R272840413**

Patient Site	Visit Visit Date	CRF CRF Page
R5017	Ae	Page_40
CD_001		40

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

Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag	N	27-APR-2010 11:51:26	Data Entry Error
1	Y	Sharon Ladenes	

Document #: **R272840413**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	Ae	Page_40 40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Taken 1	NONE OTHER DRUG	22-DEC-2009 11:58:48 Sharon Ladenes	Data Entry Error

Document #: **R285719513**

Patient Site	Visit Visit Date	CRF CRF Page
R5017 CD_001	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
Onset Date 1	06-OCT-2009 00-OCT-2009	11-FEB-2010 11:53:56 Sharon Ladenes	Data Entry Error

Document #: **R285721213**

Patient Site	Visit Visit Date	CRF CRF Page		
R5017 CD_001	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	
Date the subject completed OR withdrew f 1	26-OCT-2009 21-DEC-2009		13-JAN-2010 18:39:15 Sharon Ladenes	Data Entry Error

Discrepancy Detail Report

Document #: **R259022013**

Discrepancy ID: 93229811 Site: CD_001 Patient: R5017
Visit: SCREENING Visit Date:
CRF: PAGE_07 Section: LB Qualifying Value: 7
Field: Requisition Number 1: Row: 1
Value Text: 194-967-0027-0
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify updating requisition number to 194-967-0027-0.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R259022013

Discrepancy ID: 74010111

Site: CD_001

Patient: R5017

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: UPREG

Qualifying Value: 7

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please provide result for urine pregnancy test or select N/A.

Internal Comment:

Resolution Type: Due Diligence

Resolution Text: Developed onstudy, reported as A/E with resolve date however condition now becomes a part of medical history

Document #: R259022013

Discrepancy ID: 74010211

Site: CD_001

Patient: R5017

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: DRGSCR

Qualifying Value: 7

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please provide result for urine drug screen.

Internal Comment:

Resolution Type: Due Diligence

Resolution Text: Developed onstudy, reported as A/E with resolve date however condition now becomes a part of medical history

Document #: R259023113

Discrepancy ID: 59248211 **Site:** CD_001 **Patient:** R5017
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 3
Value Text: TOTAL HYSTERECTOMY
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please list total hysterectomy instead of bilateral oophorectomy.

Internal Comment:

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

Discrepancy ID: 73970611 **Site:** CD_001 **Patient:** R5017
Visit: SCREENING **Visit Date:**
CRF: PAGE_09 **Section:** MH **Qualifying Value:** 9
Field: Diagnosis/Procedure **Row:** 6
Value Text: CHRONIC FLATULENCE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update diagnosis/procedure term to clarify if this is an episodic/intermittent or chronic/continuing condition.

Internal Comment:

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

Document #: R259026013

Discrepancy ID: 1789624913

Site: CD_001

Patient: R5017

Visit: SCREENING

Visit Date:

CRF: PAGE_10

Section: SMOKING HISTORY

Qualifying Value: 10

Field: Comments (pharmaceuticals)

Row: 1

Value Text: CHANTIX ONCE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: It appears that the nicotine patch should be listed under the NRT section of this page and per source subject tried Chantix one time. Please review source and revise CRF page as applicable.

Internal Comment:

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

Resolution Text:

Document #: R272839113

Discrepancy ID: 34865711

Site: CD_001

Patient: R5017

Visit: PCM.1

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Start Date

Row: 1

Value Text: 20090705

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please have staff clarify handwriting for month of start and stop dates for use of benadryl. Revise as applicable.

Internal Comment:

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

Resolution Text:

Document #: R278886013

Discrepancy ID: 104387011

Site: CD_001

Patient: R5017

Visit: PCM.4

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: HYPERTENSION

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please update to Hypertension to match AE term.

Internal Comment: UPDATED

Resolution Type: Confirmed

Resolution Text: Verified. JLM 23Apr2010

Document #: R285721213

Discrepancy ID: 34867611 **Site:** CD_001 **Patient:** R5017
Visit: STUDY COMPETITION **Visit Date:**
CRF: PAGE_46 **Section:** DS **Qualifying Value:** 46
Field: Date the subject completed OR withdrew f **Row:** 1
Value Text: 20091221
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Early term visit completed on 21Dec09, please revise completion date.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Deleted CRFs Report