

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 15:50:50

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2026

Ending patient: R2026

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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

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

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

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

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Inclusion Criteria

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

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

* If No, document on Subject Eligibility Page.

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

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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

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

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.

02 The subject is a female who is pregnant or lactating.

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.

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.

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.

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.

07 The subject has a history of alcohol or substance abuse or dependence other than cigarette smoking within the past year

08 Use of any illicit drug or smoked marijuana in the last 3 months

09 The subject is unwilling to be randomized into active or placebo conditions, or be available for follow-up assessments.

10 The subject resides in a household where another member is currently participating in the study.

* If Yes, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

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="30-JUN-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other <input type="text"/>		

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="063.8"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	132
Diastolic Blood Pressure	MMHG	080
Heart Rate	BEATS / MINUTE	050
Respiratory Rate	BREATHS / MINUTE	16
Body Temperature	C	36.6
Weight	LB	182.8

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

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

Urine Drug Screen

Drug Screen Result*

Positive Negative

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at Least 5 Minutes?	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text" value="30-JUN-2009"/>	<input type="text" value="15:29"/>

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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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

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
01	TOOTHACHES DUE TO UPPER INCISORS PERI	00-00-1983	00-00-2003	<input type="checkbox"/> Ongoing
02	HIGH CHOLESTEROL	00-00-1994		<input checked="" type="checkbox"/> Ongoing
03	FIBROMYALGIA	00-00-1999		<input checked="" type="checkbox"/> Ongoing
04	MILD HYPOPIGMENTATION BILATERAL DORSA	00-00-1994		<input checked="" type="checkbox"/> Ongoing
05	TUBAL LIGATION	23-JUL-1991	23-JUL-1991	<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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Document Number

OverFlow Section For Document Number R264579013

- 1 TOOTHACHES DUE TO UPPER INCISORS PERIODONTAL DISEASE
- 2 MILD HYPOPIGMENTATION BILATERAL DORSAL HANDS

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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="16"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="25"/>	
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="2"/>	NICOTINE PATCHES 2007, GUM 2007
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="2"/>	WELLBUTRIN 1998, CHANTIX 2007
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	HYPNOTISM 1984, ACUPUNCTURE 1979
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="5"/>	COLD TURKEY 1976, 1978, 1982, 1990, 1991

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Document Number

OverFlow Section For Document Number R264579613

1 COLD TURKEY 1976, 1978, 1982, 1990, 1991

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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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
30-JUN-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
30-JUN-2009	WAS "CLEANING THE AIR" BOOKLET PROVIDED?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
<input type="text" value="14-JUL-2009"/>	<input type="text" value="13:27"/>	<input type="text" value="20"/>	<input type="text" value="3.8"/>	<input type="text"/>

Behavioral Counseling

Date	Parameter	Result	Comments
<input type="text" value="14-JUL-2009"/>	<input type="text" value="WAS BEHAVIORAL COUNSELING GIVEN?"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Questionnaires

Date

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time
Was Subject randomized? Yes No

Product Dispensation

Date

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

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

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="22-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="96"/>	<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="28-JUL-2009"/>	<input type="text" value="WEEK 2"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="60"/>	<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="05-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="65"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?	<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="80"/>	<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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Page Version No. PAGE_16 (v1, 14-APR-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	120
Diastolic Blood Pressure	MMHG	073
Heart Rate	BEATS / MINUTE	054
Respiratory Rate	BREATHS / MINUTE	20
Body Temperature	C	36.6
Weight	LB	184.0

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

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"/>
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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
26-AUG-2009	15:20	9	2.0	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

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="1"/> 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="26-AUG-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="70"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text" value="26-AUG-2009"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="09-SEP-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="56"/>	
	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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Page Version No. PAGE_21 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	131
Diastolic Blood Pressure	MMHG	073
Heart Rate	BEATS / MINUTE	061
Respiratory Rate	BREATHS / MINUTE	18
Body Temperature	C	36.5
Weight	LB	183.8

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
23-SEP-2009	15:20	13	2.7	

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?
MNWS Yes No

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

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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	<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="23-SEP-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="56"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text" value="23-SEP-2009"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="14-OCT-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="52"/>	
	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	
	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	

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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	122
Diastolic Blood Pressure	MMHG	084
Heart Rate	BEATS / MINUTE	054
Respiratory Rate	BREATHS / MINUTE	20
Body Temperature	C	36.5
Weight	LB	184.6

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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.

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
04-NOV-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
04-NOV-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
04-NOV-2009	OTHER ORAL KERATOSIS	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_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
04-NOV-2009	15:36	9	2.0	

Behavioral Counseling

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

Questionnaires

Date

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

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Page Version No. PAGE_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
04-NOV-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="70"/>	
	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="126"/>	<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="140"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	150
Diastolic Blood Pressure	MMHG	093
Heart Rate	BEATS / MINUTE	086
Respiratory Rate	BREATHS / MINUTE	16
Body Temperature	C	37.0
Weight	LB	182.8

Verified Approved Locked Frozen

Page Version No. PAGE_33 (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_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
27-JAN-2010	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
27-JAN-2010	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
27-JAN-2010	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
<input type="text" value="27-JAN-2010"/>	<input type="text" value="15:33"/>	<input type="text" value="33"/>	<input type="text" value="5.9"/>	<input type="text"/>

Behavioral Counseling

Date	Parameter	Result	Comments
<input type="text" value="27-JAN-2010"/>	<input type="text" value="WAS BEHAVIORAL COUNSELING GIVEN?"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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="27-JAN-2010"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="140"/>	<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.

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.

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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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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

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE_39 (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

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

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

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	MMHG	126
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	081
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS / MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS / MINUTE	ND
	Body Temperature	C	ND

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 <input type="text"/>	Respiratory Rate		
	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

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 #: R264579013

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	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 1	TOOTHACHES TOOTHACHES DUE TO PERIODONTAL DISEASE	02-SEP-2009 14:04:01 Amanda Lynn	Data Entry Error
Diagnosis/Procedure 1	TOOTHACHES DUE TO PERIODONTAL DISEASE TOOTHACHES DUE TO UPPER INCISORS PERIODONTAL DISEASE	14-DEC-2009 09:56:21 Cindy Riojas Prakop	Data Entry Error
Date of Onset 2		01-SEP-2009 16:01:31 Laurie Rydstrom	Row Inserted
Date of Onset 2	00-00-1994	23-SEP-2009 15:21:25 Amanda Lynn	Data Entry Error
Date of Resolution 2		01-SEP-2009 16:01:31 Laurie Rydstrom	Row Inserted
Diagnosis/Procedure 2		01-SEP-2009 16:01:31 Laurie Rydstrom	Row Inserted
Diagnosis/Procedure 2	HIGH CHOLESTEROL	23-SEP-2009 15:21:25 Amanda Lynn	Data Entry Error
Ongoing 2		01-SEP-2009 16:01:31 Laurie Rydstrom	Row Inserted
Ongoing 2	CHECKED	23-SEP-2009 15:21:25 Amanda Lynn	Data Entry Error
Sequence Number 2		01-SEP-2009 16:01:31 Laurie Rydstrom	Row Inserted
Sequence Number 2	02	23-SEP-2009 15:21:25 Amanda Lynn	Data Entry Error
Date of Onset 3	00-00-1999	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Date of Resolution 3		23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted

Document #: R264579013

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Diagnosis/Procedure 3	FIBROMYALGIA	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Ongoing 3	CHECKED	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Sequence Number 3	03	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Date of Onset 4	00-00-1994	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Date of Resolution 4		23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Diagnosis/Procedure 4	MILD PIGMENTATION OF SKIN	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Diagnosis/Procedure 4	MILD PIGMENTATION OF SKIN MILD HYPOPIGMENTATION BILATERAL DORSAL HANDS	22-OCT-2009 15:58:59 Amanda Lynn	Data Entry Error
Ongoing 4	CHECKED	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Sequence Number 4	04	23-SEP-2009 15:21:25 Amanda Lynn	Row Inserted
Date of Onset 5		21-OCT-2009 17:09:12 Diane Yann	Row Inserted
Date of Onset 5	23-JUL-1991	22-OCT-2009 15:58:59 Amanda Lynn	Data Entry Error
Date of Resolution 5		21-OCT-2009 17:09:12 Diane Yann	Row Inserted
Date of Resolution 5	23-JUL-1991	22-OCT-2009 15:58:59 Amanda Lynn	Data Entry Error
Diagnosis/Procedure 5		21-OCT-2009 17:09:12 Diane Yann	Row Inserted

Document #: R264579013

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Diagnosis/Procedure 5	TUBAL LIGATION	22-OCT-2009 15:58:59	Data Entry Error Amanda Lynn
Ongoing 5		21-OCT-2009 17:09:12	Row Inserted Diane Yann
Sequence Number 5		21-OCT-2009 17:09:12	Row Inserted Diane Yann
Sequence Number 5	05	22-OCT-2009 15:58:59	Data Entry Error Amanda Lynn

Document #: R264579613

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Screening	Page_10 10

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

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (pharmaceuticals)) (5) 1	WELBUTRIN 1998, CHANTIX 2007 WELLBUTRIN 1998, CHANTIX 2007	09-MAR-2010 09:37:06 Kryisia Magnuson	ODM/SEC Welbutrin to Wellbutrin. KAY 09Mar2010.

Document #: R264581313

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Screening	Page_11 11

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

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings 3	UPPER INCISORS PROSTHESIS; NO OTHER LESION	18-AUG-2009 10:21:28 Amanda Lynn	Data Entry Error
Findings* 3	YES	18-AUG-2009 10:19:41 Amanda Lynn	Data Entry Error
Findings* 3	YES NO	18-AUG-2009 10:21:28 Amanda Lynn	Data Entry Error

Document #: R264585313

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	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
Findings 1	UPPER INCISORS PROSTHESIS; NO OTHER LESION UPPER INCISORS PROSTHESIS; NO OTHER LESION/NCS	14-DEC-2009 10:08:40 Cindy Riojas Prakop	Data Entry Error
Findings 2		10-DEC-2009 12:12:28 Diane Yann	Row Inserted
Findings 2	HYPOPIGMENTATION BILATERAL DORSAL HANDS/NCS	08-JAN-2010 11:40:23 Amanda Lynn	Data Entry Error
Sequence Number 2		10-DEC-2009 12:12:28 Diane Yann	Row Inserted
Sequence Number 2	02	08-JAN-2010 11:40:23 Amanda Lynn	Data Entry Error
Findings 3	HYPOPIGMENTATION BILATERAL DORSAL HANDS/NCS	14-DEC-2009 10:09:30 Cindy Riojas Prakop	Row Inserted
Findings 3	HYPOPIGMENTATION BILATERAL DORSAL HANDS/NCS	08-JAN-2010 11:40:23 Amanda Lynn	Data Entry Error
Findings 3	<Row Deleted>	24-MAR-2010 11:42:49 Kryisia Magnuson	Data Entry Error
Sequence Number 3	02	14-DEC-2009 10:09:30 Cindy Riojas Prakop	Row Inserted
Sequence Number 3	02	08-JAN-2010 11:40:23 Amanda Lynn	Data Entry Error
Sequence Number 3	<Row Deleted>	24-MAR-2010 11:42:49 Kryisia Magnuson	Data Entry Error

Document #: R266289813

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Ip, Week 6	Page_20 20

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	70	22-OCT-2009 16:01:04 Amanda Lynn	Data Entry Error

Document #: R274794613

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Ip, Week 10	Page_24 24

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
If Subject was not compliant, approximat (5) 1	112 56	16-NOV-2009 10:11:57 Amanda Lynn	Data Entry Error

Document #: R279096313

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Ip, Week 16	Page_29 29

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	29	Ip, Week 16

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	NO YES	14-DEC-2009 11:42:45 Cindy Riojas Prakop	Data Entry Error
Does the subject have any abnormal findi 1	YES NO	08-JAN-2010 11:50:01 Amanda Lynn	Data Entry Error
Findings 1	UPPER INCISORS PROSTHESIS; NO OTHER LESION/NCS	14-DEC-2009 11:43:01 Cindy Riojas Prakop	Row Inserted
Findings 1	UPPER INCISORS PROSTHESIS; NO OTHER LESION/NCS	08-JAN-2010 11:49:01 Amanda Lynn	Data Entry Error
Findings 1	<Row Deleted>	24-MAR-2010 11:43:22 Krysia Magnuson	Data Entry Error
Sequence Number 1	01	14-DEC-2009 11:43:01 Cindy Riojas Prakop	Row Inserted
Sequence Number 1	01	08-JAN-2010 11:49:01 Amanda Lynn	Data Entry Error
Sequence Number 1	<Row Deleted>	24-MAR-2010 11:43:22 Krysia Magnuson	Data Entry Error
Findings 2	HYPOPIGMENTATION BILATERAL DORSAL HANDS/NCS	14-DEC-2009 11:43:01 Cindy Riojas Prakop	Row Inserted
Findings 2	HYPOPIGMENTATION BILATERAL DORSAL HANDS/NCS	08-JAN-2010 11:49:01 Amanda Lynn	Data Entry Error
Findings 2	<Row Deleted>	24-MAR-2010 11:43:22 Krysia Magnuson	Data Entry Error
Sequence Number 2	02	14-DEC-2009 11:43:01 Cindy Riojas Prakop	Row Inserted

Document #: R279096313

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Ip, Week 16	Page_29 29

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	29	Ip, Week 16

Group #	Group Name
2	MH1

Sequence Number 2	02	08-JAN-2010 11:49:01	Data Entry Error Amanda Lynn
Sequence Number 2	<Row Deleted>	24-MAR-2010 11:43:22	Data Entry Error Kryisia Magnuson

Document #: R264588313

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	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	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change

Document #: R271136613

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Pcm.3	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	R	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC1 Text 1	RESPIRATORY SYSTEM, R	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Code 1	R05	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC2 Text 1	COUGH AND COLD PREPARATIONS, R05	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Code 1	R05F	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC3 Text 1	COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, R05F	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC4 Code 1	R05FA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
ATC4 Text 1	OPIUM DERIVATIVES AND EXPECTORANTS, R05FA	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug Modified Reported Term 1	MUCINEX PM MUCINEX DM	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Drug name 1	MUCINEX PM MUCINEX DM	26-APR-2010 12:24:36 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 26Apr2010
Preferred Term 1	TUSSIN DM	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Preferred Term Code 1	00979901001	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change
Trade Name 1	MUCINEX DM	26-APR-2010 12:25:24 Joanne Mccaigue	Data Change

Document #: R271136613

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Pcm.3	Page_39

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

Group #	Group Name
1	CM1

Trade Name Code	26-APR-2010 12:25:24	Data Change
1	00979901078	Joanne Mccaigue

Document #: R271136713

Patient Site	Visit Visit Date	CRF CRF Page
R2026 L0689282_2	Pcm.4	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Frequency 1	EVERY DAY ONCE	14-DEC-2009 11:44:28 Cindy Riojas Prakop	Data Entry Error

Discrepancy Detail Report

Document #: R264579013

Discrepancy ID: 1735675513 Site: L0689282_2 Patient: R2026
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 1
Value Text: TOOTHACHES DUE TO UPPER INCISORS PERIODONTAL DISEASE
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: PE finding of prosthetic bilateral incisors, upper should be listed.
Internal Comment: corrected to "upper incisors prosthetic"
Resolution Type: No Action Required
Resolution Text:

Discrepancy ID: 1735675713 Site: L0689282_2 Patient: R2026
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 2
Value Text: HIGH CHOLESTEROL
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per NTF please add all ongoing Med Hx (should be updated to relevant by the PI)
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1777341413 Site: L0689282_2 Patient: R2026
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 4
Value Text: MILD HYPOPIGMENTATION BILATERAL DORSAL HANDS
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Medical terminology is hypopigmentation, mild, bilateral dorsal hands. See PE finding.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1777352813 Site: L0689282_2 Patient: R2026
Visit: SCREENING Visit Date:
CRF: PAGE_09 Section: MH Qualifying Value: 9
Field: Diagnosis/Procedure Row: 5
Value Text: TUBAL LIGATION
Type: MANUAL Status: CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please add tubal ligation, 23Jul1991
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R266289813

Discrepancy ID: 1735677313 **Site:** L0689282_2 **Patient:** R2026
Visit: IP, WEEK 6 **Visit Date:**
CRF: PAGE_20 **Section:** STATUS REVIEW **Qualifying Value:** 20
Field: If Subject was not compliant, approximat **Row:** 1
Value Text: 70
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please add information when week 6 diary available
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R274794613

Discrepancy ID: 1791883913 **Site:** L0689282_2 **Patient:** R2026
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: 56
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify value. Please see diary. Return questionnaire captures 2 weeks worth of information.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R279096313

Discrepancy ID: 18333911 **Site:** L0689282_2 **Patient:** R2026
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_29 **Section:** PE **Qualifying Value:** 29
Field: Does the subject have any abnormal findi **Row:** 1
Value Text: NO
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please add the findings noted on the PE exam and add NCS to each per source.
Internal Comment: added findings on pe
Resolution Type: No Action Required
Resolution Text:

Document #: R271136713

Discrepancy ID: 18335011

Site: L0689282_2

Patient: R2026

Visit: PCM.4

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Frequency

Row: 1

Value Text: ONCE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review, should the frequency be one time?

Internal Comment: corrected to one time

Resolution Type: No Action Required

Resolution Text:

Deleted CRFs Report