

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 16:35:59

Report Parameters

Site: CD_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R5027

Ending patient: R5027

Legend: How different values appear in the report

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

RDC CASE REPORT FORM

Information Correct Yes No

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

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

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

for

SWEDISH MATCH AB
ROSENLUNDSGATAN 36
SE-118 85 STOCKHOLM
SWEDEN

by

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

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Exclusion Criteria

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

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

* If Yes, document on Subject Eligibility Page.

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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	

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="21-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 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="067.8"/>

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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

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	107
Diastolic Blood Pressure	MMHG	70
Heart Rate	BEATS/MINUTE	63
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.5
Weight	LB	167.8

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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	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="21-JUL-2009"/>	<input type="text" value="10:48"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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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

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	IUD INSERTION	00-00-2008	18-NOV-2009	<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

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Swedish Match AB

Protocol Number: SM 08-01

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="21"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="13"/>	
Has subject used smokeless tobacco in the past?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="7"/>	5 TIMES USING PATCH AND 2 TIMES USING GUM
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"/>	WELLBUTRIN
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="1"/>	HYPNOTISM
Has the subject made any other attempts to quit smoking? List details of other quit attemps in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	

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Document Number

OverFlow Section For Document Number R260837913

1 5 TIMES USING PATCH AND 2 TIMES USING GUM

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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
21-JUL-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
21-JUL-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
21-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.

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

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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
28-JUL-2009	12:37	15	3.0	

Behavioral Counseling

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

Questionnaires

Date

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

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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

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
ND	WEEK 1	Was Subject contacted by telephone?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	NO RECORD OF PE
		Was Subject's smoking status reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
		Was Subject's use of study product reviewed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
		Approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	
		Was Behavioral Counseling Given?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Date	Scheduled Timepoint	Parameter	Result	Comments
10-AUG-2009	WEEK 2	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	
		Approximately how many cigarettes did the subject smoke that week?	49	
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Date	Scheduled Timepoint	Parameter	Result	Comments
17-AUG-2009	WEEK 3	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	
		Approximately how many cigarettes did the subject smoke that week?	35	
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

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

Document Number

OverFlow Section For Document Number R275396313

1 NO RECORD OF PHONE CALL ATTEMPTS MADE

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	112
Diastolic Blood Pressure	MMHG	63
Heart Rate	BEATS/MINUTE	70
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.2
Weight	LB	169.0

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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.

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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
08-SEP-2009	12:02	2	0.9	

Behavioral Counseling

Date	Parameter	Result	Comments
08-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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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 logs

1.0 g of snus or matching placebo logs

Status Review

Date

Parameter

Result

Comments

Was Subject's smoking status reviewed? Yes No

Was Subject compliant? Yes No

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

Was Subject asked HDYF? question? Yes No

Diary Distribution

Date

Did subject receive diary and usage instructions?

Yes No

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Links to Discrepancy and Audit Sections

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

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Page Version No. PAGE_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	120
Diastolic Blood Pressure	MMHG	67
Heart Rate	BEATS/MINUTE	67
Respiratory Rate	BREATHS/MINUTE	24
Body Temperature	C	36.8
Weight	LB	170.8

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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
05-OCT-2009	17:02	2	0.9	

Behavioral Counseling

Date	Parameter	Result	Comments
05-OCT-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)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="0"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="05-OCT-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date Did subject receive diary and usage instructions? Yes No

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Page Version No. PAGE_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" value="26-OCT-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject instructed to cut down on product use during upcoming Weeks 14-16 to avoid a too abrupt ending of nicotine uptake?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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	70
Heart Rate	BEATS/MINUTE	55
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.8
Weight	LB	172.2

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

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
16-NOV-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
16-NOV-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
16-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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
16-NOV-2009	18:27	2	0.9	

Behavioral Counseling

Date	Parameter	Result	Comments
16-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

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="16-NOV-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 checked="" 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 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 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 checked="" 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 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text" value="SUBJECT EARLY TERMINATION"/>
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

OverFlow Section For Document Number R285715513

1 SUBJECT EARLY TERMINATION DUE TO SAE

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

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	110
Diastolic Blood Pressure	MMHG	67
Heart Rate	BEATS/MINUTE	71
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	37.0
Weight	LB	184.6

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
19-FEB-2010	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
19-FEB-2010	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
19-FEB-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

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
19-FEB-2010	11:40	7	1.7	

Behavioral Counseling

Date	Parameter	Result	Comments
19-FEB-2010	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires

Date

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

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="19-FEB-2010"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="1"/>	<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_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

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

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

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[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.

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

Verified Approved Locked Frozen

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

Document Number

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 #: R260836413

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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
Requisition Number 1: (1) 1	202967-0034-0 202-967-0034-0	09-OCT-2009 16:32:10 Sharon Ladenes	Data Entry Error

Document #: R260837113

Patient Site	Visit Visit Date	CRF CRF Page
R5027	Screening	Page_09
CD_001		09

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Onset 1	00-NOV-2006 <Row Deleted>	22-OCT-2009 20:27:49 Sharon Ladenes	Data Entry Error
Date of Onset 1	00-00-2008	09-MAR-2010 19:03:08 Sharon Ladenes	Row Inserted
Date of Resolution 1	00-NOV-2006 <Row Deleted>	22-OCT-2009 20:27:49 Sharon Ladenes	Data Entry Error
Date of Resolution 1	18-NOV-2009	09-MAR-2010 19:03:08 Sharon Ladenes	Row Inserted
Date of Resolution 1	18-NOV-2009 00-00-2008	18-MAR-2010 11:16:33 Sharon Ladenes	Data Entry Error
Date of Resolution 1	00-00-2008 18-NOV-2009	25-MAR-2010 11:00:58 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 1	HEART ABLASIA <Row Deleted>	22-OCT-2009 20:27:49 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 1	IUD INSERTION AND REMOVAL	09-MAR-2010 19:03:08 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 1	IUD INSERTION AND REMOVAL IUD INSERTION	18-MAR-2010 11:16:33 Sharon Ladenes	Data Entry Error
Does the subject have any relevant medication 1	YES NO	22-OCT-2009 20:27:49 Sharon Ladenes	Data Entry Error
Does the subject have any relevant medication 1	NO YES	09-MAR-2010 19:03:08 Sharon Ladenes	Data Entry Error
Ongoing 1	<Row Deleted>	22-OCT-2009 20:27:49 Sharon Ladenes	Data Entry Error
Ongoing 1		09-MAR-2010 19:03:08 Sharon Ladenes	Row Inserted

Document #: R260837113

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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

Sequence Number 1	1 <Row Deleted>	22-OCT-2009 20:27:49 Sharon Ladenes	Data Entry Error
Sequence Number 1	1	09-MAR-2010 19:03:08 Sharon Ladenes	Row Inserted
Date of Onset 2	18-NOV-2009	18-MAR-2010 11:16:33 Sharon Ladenes	Row Inserted
Date of Onset 2	18-NOV-2009 <Row Deleted>	25-MAR-2010 11:00:58 Sharon Ladenes	Data Entry Error
Date of Resolution 2	18-NOV-2009	18-MAR-2010 11:16:33 Sharon Ladenes	Row Inserted
Date of Resolution 2	18-NOV-2009 <Row Deleted>	25-MAR-2010 11:00:58 Sharon Ladenes	Data Entry Error
Diagnosis/Procedure 2	IUD REMOVAL	18-MAR-2010 11:16:33 Sharon Ladenes	Row Inserted
Diagnosis/Procedure 2	IUD REMOVAL <Row Deleted>	25-MAR-2010 11:00:58 Sharon Ladenes	Data Entry Error
Ongoing 2		18-MAR-2010 11:16:33 Sharon Ladenes	Row Inserted
Ongoing 2	<Row Deleted>	25-MAR-2010 11:00:58 Sharon Ladenes	Data Entry Error
Sequence Number 2	2	18-MAR-2010 11:16:33 Sharon Ladenes	Row Inserted
Sequence Number 2	2 <Row Deleted>	25-MAR-2010 11:00:58 Sharon Ladenes	Data Entry Error

Document #: R260837913

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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
Attempted to quit (Nicotine Replacement) (2) 1	NO YES	11-MAR-2010 15:25:54 Stephanie Felton	Data Entry Error
Attempted to quit (Other attempts) (5) 1	YES	25-MAR-2010 11:05:58 Sharon Ladenes	Data Entry Error
Attempted to quit (Other attempts) (5) 1	NO	25-MAR-2010 11:07:12 Sharon Ladenes	Data Entry Error
Attempted to quit (Other cessation aids) (4) 1	YES NO	11-MAR-2010 15:25:54 Stephanie Felton	Data Entry Error
Attempted to quit (Other cessation aids) (4) 1	NO YES	25-MAR-2010 11:05:58 Sharon Ladenes	Data Entry Error
Comments (NRT) (4) 1	5 TIMES USING PATCH AND 2 TIMES USING GUM	11-MAR-2010 15:25:54 Stephanie Felton	Data Entry Error
Comments (other attemps) (7) 1	HYPOTISM HYPOTISM	22-OCT-2009 20:28:54 Sharon Ladenes	Data Entry Error
Comments (other attemps) (7) 1	HYPOTISM HYPNOTISM.	09-MAR-2010 13:07:17 Sharon Ladenes	Data Entry Error
Comments (other attemps) (7) 1	HYPNOTISM.	25-MAR-2010 11:05:58 Sharon Ladenes	Data Entry Error
Comments (other cessation aids) (6) 1	5 TIMES USING PATCH AND 2 TIMES USING GUM	11-MAR-2010 15:25:54 Stephanie Felton	Data Entry Error

Document #: R260837913

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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

Comments (other cessation aids) (6) 1	HYPNOTISM	25-MAR-2010 11:05:58 Sharon Ladenes	Data Entry Error
--	-----------	--	------------------

Comments (pharmaceuticals) (5) 1	WELLBUTRIM WELLBUTRIN	17-MAR-2010 16:40:45 Kryisia Magnuson	ODM/SEC Wellbutrim to Wellbutrin. KAY 17Mar2010.
-------------------------------------	--------------------------	--	---

If Yes, how many (nicotine replacement) (3) 1	7	11-MAR-2010 15:25:54 Stephanie Felton	Data Entry Error
--	---	--	------------------

If Yes, how many (other cessation aids) (5) 1	5	11-MAR-2010 15:25:54 Stephanie Felton	Data Entry Error
--	---	--	------------------

If Yes, how many (other cessation aids) (5) 1	1	25-MAR-2010 11:05:58 Sharon Ladenes	Data Entry Error
--	---	--	------------------

If yes, how many (other attempts to quit) (6) 1	1	25-MAR-2010 11:05:58 Sharon Ladenes	Data Entry Error
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Document #: R260838713

Patient Site	Visit Visit Date	CRF CRF Page		
R5027 CD_001	Baseline, Week 0	Page_15 15		
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit	
Sc	Page number	15	Baseline, Week 0	
Group #	Group Name			
1	SC			
Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Actual Time 1	1256 1254		09-MAR-2010 12:01:43 Sharon Ladenes	Data Entry Error

Document #: R275396313

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Approximately how many cigarettes did th (10) 1	70	09-MAR-2010 11:11:06 Sharon Ladenes	Data Entry Error
Comments (contacted by phone) (1) 1	NO RECORD OF PHONE CALL ATTEMPTS MADE	15-MAR-2010 15:15:40 Stephanie Felton	Data Entry Error
Comments (contacted by phone) (1) 1	NO RECORD OF PHONE CALL ATTEMPTS MADE	06-MAY-2010 13:06:45 Sharon Ladenes	Data Entry Error
Comments (contacted by phone) (1) 1	NO RECORD OF PHONE CALL ATTEMPTS MADE	06-MAY-2010 13:44:19 Sharon Ladenes	Data Entry Error
Date 1	03-AUG-2009 ND	06-MAY-2010 13:06:45 Sharon Ladenes	Data Entry Error
Was Behavioral Counseling Given (6) 1	YES	09-MAR-2010 11:11:06 Sharon Ladenes	Data Entry Error
Was Subject contacted by telephone (1) 1	YES NO	09-MAR-2010 11:11:06 Sharon Ladenes	Data Entry Error
Was Subject's smoking status reviewed (2) 1	YES	09-MAR-2010 11:11:06 Sharon Ladenes	Data Entry Error
Was Subject's use of study product review (3) 1	NO YES	23-OCT-2009 10:47:39 Sharon Ladenes	Data Entry Error

Document #: R275396313

Patient Site	Visit Visit Date	CRF CRF Page		
R5027 CD_001	Sptp, Weeks 1-4	Page_16 16		
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit	
Status Review	Page number	16	Sptp, Weeks 1-4	
Group #	Group Name			
1	CHKYN			
Was Subject's use of study product review (3) 1	YES	09-MAR-2010 11:11:06	Data Entry Error	Sharon Ladenes

Document #: R275396313

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Was Subject's use of study product review (3) 1	NO YES	23-OCT-2009 10:47:39 Sharon Ladenes	Data Entry Error

Document #: R275396313

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Sptp, Weeks 1-4	Page_16 16

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

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Was Subject's use of study product review (3) 1	YES	23-OCT-2009 10:47:39 Sharon Ladenes	Data Entry Error

Document #: R275397013

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	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
Was Subject compliant (4) 1	NO YES	18-JAN-2010 11:56:25 Sharon Ladenes	Pass1

Document #: R282991413

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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
Was Subject compliant (4) 1	NO YES	18-JAN-2010 11:58:10 Sharon Ladenes	Data Entry Error

Document #: R282991813

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Ip, Week 16	Page_27 27

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	27	Ip, Week 16

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Were there any clinically significant la (1) 1	NO	09-MAR-2010 11:13:27 Sharon Ladenes	Data Entry Error

Document #: R285715513

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Fu, Week 20 & 24	Page_32 32

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	09-MAR-2010 12:05:12 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	09-MAR-2010 12:08:54 Sharon Ladenes	Data Entry Error

Document #: R285715513

Patient Site	Visit Visit Date	CRF CRF Page	
R5027 CD_001	Fu, Week 20 & 24	Page_32 32	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32	Fu, Week 20 & 24

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (HDYF) (8) 1		09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Comments (behavioral counseling) (6) 1		09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Comments (compliant) (4) 1		09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Comments (contacted by phone) (1) 1		09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Comments (how many cigarettes) (5) 1		09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Comments (smoking status reviewed) (2) 1		09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Date 1	14-DEC-2009	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
If Subject was not compliant, approximat (5) 1	0	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
If Subject was not compliant, approximat (5) 1	0	16-MAR-2010 13:20:23 Sharon Ladenes	Investigator Correction
Scheduled Timepoint 1	WEEK 20	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Was Behavioral Counseling Given (6) 1	YES	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted

Document #: R285715513

Patient Site	Visit Visit Date	CRF CRF Page	
R5027 CD_001	Fu, Week 20 & 24	Page_32 32	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32	Fu, Week 20 & 24

Group #	Group Name		
1	CHKYN		
Was Subject asked HDYF? (8) 1	YES	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Was Subject compliant (4) 1	YES	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Was Subject contacted by telephone (1) 1	YES	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted
Was Subject's smoking status reviewed (2) 1	YES	09-MAR-2010 12:08:54 Sharon Ladenes	Row Inserted

Document #: R285715513

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Fu, Week 20 & 24	Page_32 32

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	32.1	Fu, Week 20 & 24

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
DCM Blank flag 1	N Y		09-MAR-2010 11:13:36 Diane Yann	Key Change

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Comments (contacted by phone) (1) 1	SUBJECT EARLY TERM DUE TO SAE SUBJECT EARLY TERMINATION DUE TO SAE		18-MAR-2010 11:23:00 Sharon Ladenes	Data Entry Error
Date 1	12-JAN-2010 ND		18-MAR-2010 11:23:00 Sharon Ladenes	Data Entry Error

Document #: R295265213

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Fu, Week 28	Page_36 36

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pe	Page number	36	Fu, Week 28

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	09-MAR-2010 12:00:39 Sharon Ladenes	Data Entry Error
Findings 1	PE CONSISTENT WITH PREGNANCY	09-MAR-2010 12:00:39 Sharon Ladenes	Row Inserted
Sequence Number 1	1	09-MAR-2010 12:00:39 Sharon Ladenes	Row Inserted

Document #: R260840013

Patient Site	Visit Visit Date	CRF CRF Page
R5027	Pcm	Page_39
CD_001		39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	03-SEP-2009 14:44:20 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	03-SEP-2009 14:44:54 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	N Y	04-JAN-2010 17:36:47 Sharon Ladenes	Data Entry Error
DCI Blank Flag 1	Y N	04-JAN-2010 17:36:55 Sharon Ladenes	Data Entry Error

Document #: R260840013

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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	A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Code 1	A08	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Text 1	ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, A08	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Code 1	A08A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Text 1	ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, A08A	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Code 1	A08AA	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Text 1	CENTRALLY ACTING ANTI OBESITY PRODUCTS, A08AA	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Dose 1	10	04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
Dose 1	10 1	04-JAN-2010 17:35:03 Sharon Ladenes	Data Entry Error
Dose 1	1	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Drug Modified Reported Term 1	ADAPOT ADIPEX	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	VITAMIN	04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted

Document #: R260840013

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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

Drug name 1	VITAMIN PRENATAL VITAMINS	04-JAN-2010 17:35:03 Sharon Ladenes	Data Entry Error
Drug name 1	ADAPOT	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Drug name 1	ADAPOT ADIPEX	13-APR-2010 11:37:02 Sharon Ladenes	Data Entry Error
Frequency 1	EVERY DAY	04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
Frequency 1	EVERY DAY	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	NO	03-SEP-2009 14:44:54 Sharon Ladenes	Row Inserted
Has the subject taken any medications pr 1	NO YES	04-JAN-2010 17:29:34 Sharon Ladenes	Data Entry Error
Has the subject taken any medications pr 1	YES	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Indication 1	SUPPLEMENT	04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
Indication 1	SUPPLEMENT PREGNANCY	04-JAN-2010 17:35:03 Sharon Ladenes	Data Entry Error
Indication 1	WEIGHT LOSS	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Ongoing 1		04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
Ongoing 1	CHECKED	04-JAN-2010 17:35:03 Sharon Ladenes	Data Entry Error
Ongoing 1		04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Preferred Term 1	PHENTERMINE	26-APR-2010 10:36:00 Carol Kraucyk	Data Change

Document #: R260840013

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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

Preferred Term Code 1	00131701001	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Start Date 1	01-JUL-2009	04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
Start Date 1	01-JUL-2009 13-DEC-2009	04-JAN-2010 17:35:03 Sharon Ladenes	Data Entry Error
Start Date 1	00-00-2008	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Stop Date 1	13-JUL-2009	04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
Stop Date 1	13-JUL-2009	04-JAN-2010 17:35:03 Sharon Ladenes	Data Entry Error
Stop Date 1	17-JUL-2009	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
Trade Name 1	ADIPEX /00131701/	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Trade Name Code 1	00131701002	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Unit 1	TABLET	04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
Unit 1	TABLET	04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
other, specify (frequency) 1		04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
other, specify (frequency) 1		04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted
other, specify (unit) 1		04-JAN-2010 17:29:34 Sharon Ladenes	Row Inserted
other, specify (unit) 1		04-JAN-2010 17:36:55 Sharon Ladenes	Row Inserted

Document #: R267109413

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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
Adverse Event 1	SORE LIP IRRITATION INNER UPPER LIP	05-OCT-2009 14:22:00 Sharon Ladenes	Pass1
Outcome to Date 1	RECOVERED	05-OCT-2009 14:22:36 Sharon Ladenes	Data Entry Error

Document #: R267109513

Patient Site	Visit Visit Date	CRF CRF Page
R5027	Ae.1	Page_40
CD_001		

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
0	CRF Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	N Y	05-OCT-2009 14:23:01 Sharon Ladenes	Key Change
DCI Blank Flag 1	Y N	04-JAN-2010 17:25:04 Sharon Ladenes	Data Entry Error

Document #: R267109513

Patient Site	Visit Visit Date	CRF CRF Page
R5027 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
Action Taken 1	OTHER DRUG DISCONTINUATION	18-MAR-2010 20:26:05 Sharon Ladenes	Data Entry Error
Onset Date 1	00-SEP-2009 13-DEC-2009	11-MAR-2010 14:14:09 Linda Jordan	Data Entry Error

Document #: R267109613

Patient Site	Visit Visit Date	CRF CRF Page
R5027 CD_001	Ae.2	Page_40

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

Group #	Group Name
1	AE1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Action Specify 1	CLEANSED WITH COTTON SWAB	11-MAR-2010 14:16:28 Linda Jordan	Data Entry Error
Action Taken 1	OTHER TREATMENT NONE	09-MAR-2010 11:17:26 Sharon Ladenes	Data Entry Error
Adverse Event 1	BLOOD IN LEFT EAR BLEEDING FROM LEFT EAR CANAL	05-OCT-2009 14:23:21 Sharon Ladenes	Pass1

Document #: R288467313

Patient Site	Visit	CRF
R5027	Visit Date	CRF Page
CD_001	Study Competition	Page_46
		46

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

Group #	Group Name
1	DS

Field	Changed From	Impact on	On	Reason
Row	Changed To	resequence	By	Comment
AE specify 1	PREGNANCY		11-MAR-2010 14:36:37 Stephanie Felton	Data Entry Error
AE specify 1	PREGNANCY		18-MAR-2010 11:38:09 Sharon Ladenes	Data Entry Error
Reason for withdrawal 1	AE WITHDRAWN		11-MAR-2010 14:36:37 Stephanie Felton	Data Entry Error
Reason for withdrawal 1	WITHDRAWN AE		18-MAR-2010 11:38:09 Sharon Ladenes	Data Entry Error

Discrepancy Detail Report

Document #: R260836413

Discrepancy ID: 1766248313

Site: CD_001

Patient: R5027

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: LB

Qualifying Value: 7

Field: Requisition Number 1:

Row: 1

Value Text: 202-967-0034-0

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please add a dash to req. number

Internal Comment:

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

Resolution Text:

Document #: R260837913

Discrepancy ID: 1766248913 **Site:** CD_001 **Patient:** R5027
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: Comments (other attempts) **Row:** 1
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Hypnosis is classified as other smoking cessation aid. Please move data (hypnotism, 1 attempt) to other smoking cessation aids section.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 82864511 **Site:** CD_001 **Patient:** R5027
Visit: SCREENING **Visit Date:**
CRF: PAGE_10 **Section:** SMOKING HISTORY **Qualifying Value:** 10
Field: Comments (other cessation aids) **Row:** 1
Value Text: HYPNOTISM
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please move these up to the NRT section, also change the total number of times.
Internal Comment: Updated CRF, verified source
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R260838713

Discrepancy ID: 1766249513 **Site:** CD_001 **Patient:** R5027
Visit: BASELINE, WEEK **Visit Date:**
CRF: PAGE_15 **Section:** SC **Qualifying Value:** 15
Field: Actual Time **Row:** 1
Value Text: 1254
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per sponsor instructions, time of first use should be entered, please review source and
revise CRF page per previous query.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R282991813

Discrepancy ID: 80749011

Site: CD_001

Patient: R5027

Visit: IP, WEEK 16

Visit Date:

CRF: PAGE_27

Section: LB

Qualifying Value: 27

Field: Were there any clinically significant la

Row: 1

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: please answer the question.

Internal Comment:

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

Resolution Text:

Document #: R285715513

Discrepancy ID: 86544611 **Site:** CD_001 **Patient:** R5027
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32.1
Field: Comments (contacted by phone) **Row:** 1
Value Text: SUBJECT EARLY TERMINATION DUE TO SAE
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update so as not to use abbreviations. (TERM).

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

Discrepancy ID: 86544811 **Site:** CD_001 **Patient:** R5027
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32.1
Field: Date **Row:** 1
Value Text: ND
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter "ND" for date if assessment was not completed.

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

Discrepancy ID: 80753111 **Site:** CD_001 **Patient:** R5027
Visit: FU, WEEK 20 & 2 **Visit Date:**
CRF: PAGE_32 **Section:** STATUS REVIEW **Qualifying Value:** 32.1
Field: **Row:**
Value Text:
Type: MANUAL HEADER **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please enter the schedule date and check no for the first question add comment and leave other questions blank.

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

Document #: R260840013

Discrepancy ID: 98560811

Site: CD_001

Patient: R5027

Visit: PCM

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Drug name

Row: 1

Value Text: ADIPEX

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify drug name.

Internal Comment:

Resolution Type: Confirmed

Resolution Text: Verified. JLM 20Apr2010

Document #: R288467313

Discrepancy ID: 80760311

Site: CD_001

Patient: R5027

Visit: STUDY COMPETION **Visit Date:**

CRF: PAGE_46

Section: DS

Qualifying Value: 46

Field: Reason for withdrawal

Row: 1

Value Text: AE

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please update to Adverse Event with the specification of 'Pregnancy'. If subject withdrew consent due to the AE, the AE is the true reason for withdrawal. **Please update Action Taken for AE of Pregnancy to 'Discontinuation of Drug Therapy'.

Internal Comment:

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

Resolution Text:

Deleted CRFs Report