

CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 15:12:38

Report Parameters

Site: L0689282_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2005

Ending patient: R2005

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)

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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Inclusion Criteria

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

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

* If No, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Exclusion Criteria

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

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

* If Yes, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="12-MAR-2009"/>	<input type="text" value="(b) (6)"/>	<input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	<input type="checkbox"/> Hispanic or Latino <input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other <input type="text"/>		

Body Measurements

Were Body Measurements Collected? Yes No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="66.4"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	072
Heart Rate	BEATS/MINUTE	058
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	36.8
Weight	LB	210.4

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: 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="12-MAR-2009"/>	<input type="text" value="09:18"/>

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

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
				<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
				<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="17"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="11"/>	
Has subject used smokeless tobacco in the past?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject attempted to quit with the use of Pharmaceuticals other than NRTs? List details of other pharmaceuticals used in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	REPORTS USING ZYBAN ONCE DAILY BEGINNING JANUARY OF 2000 AND ENDING JULY OF 2000 FOR SMOKING
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="2"/>	TRIED COLD TURKEY IN JANUARY 1984 AND JULY 2000.

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OverFlow Section For Document Number R241106513

- 1 REPORTS USING ZYBAN ONCE DAILY BEGINNING JANUARY OF 2000 AND ENDING JULY OF 2000 FOR SMOKING CESSATION PURPOSES.

- 2 TRIED COLD TURKEY IN JANUARY 1984 AND JULY 2000.

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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
12-MAR-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
12-MAR-2009	EXPOSED DENTAL CERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
12-MAR-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
12-MAR-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
12-MAR-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
24-MAR-2009	11:44	8	3.5	

Behavioral Counseling

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

Questionnaires

Date

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Randomization

Date Actual Time

Was Subject randomized? Yes No

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<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

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="31-MAR-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="27"/>	<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="07-APR-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="63"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="14-APR-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="28"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Date Scheduled Timepoint

Parameter

Result

Comments

Was Subject contacted by telephone?

Yes No

Was Subject's smoking status reviewed?

Yes No

Was Subject's use of study product reviewed?

Yes No

Approximately how many cigarettes did the subject smoke that week?

Was Behavioral Counseling Given?

Yes No

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

Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	123
Diastolic Blood Pressure	MMHG	069
Heart Rate	BEATS/MINUTE	052
Respiratory Rate	BREATHS/MINUTE	018
Body Temperature	C	036.5
Weight	LB	213.0

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
05-MAY-2009	08:49	1	0.7	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="0"/> logs
1.0 g of snus or matching placebo	<input type="text" value="1"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="05-MAY-2009"/>	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 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="05-MAY-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="19-MAY-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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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	116
Diastolic Blood Pressure	MMHG	078
Heart Rate	BEATS/MINUTE	055
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.4
Weight	LB	212.4

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
08-JUN-2009	07:27	1	0.7	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Product Dispensation

Date

Product	Amount Dispensed
0.5 g of snus or matching placebo	<input type="text" value="0"/> logs
1.0 g of snus or matching placebo	<input type="text" value="2"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="08-JUN-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="23-JUN-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input 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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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	121
Diastolic Blood Pressure	MMHG	078
Heart Rate	BEATS/MINUTE	052
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.3
Weight	LB	213.4

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_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
14-JUL-2009	11:56	2	0.9	

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

Page Version No. PAGE_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="14-JUL-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject compliant?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text"/>	
	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

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 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"/>

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	125
Diastolic Blood Pressure	MMHG	069
Heart Rate	BEATS/MINUTE	052
Respiratory Rate	BREATHS/MINUTE	20
Body Temperature	C	36.3
Weight	LB	217.2

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

Page Version No. PAGE_35 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
06-OCT-2009	11:47	1	0.7	

Behavioral Counseling

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

Questionnaires

Date

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

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="06-OCT-2009"/>	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 Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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

Document Number

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

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

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

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

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

Comments

Date Actual Time

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

Comments

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

Verified Approved Locked Frozen

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

Document Number

Appendix: Audit and Discrepancy Information

Audit History Report

This section lists audited data that meets the parameters set when the report was run. It may not include all of the audited data in a particular CRF. Refer to the documentation for a complete description of the parameters that can affect this report.

Document #: R239712913

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_01 01

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Header	Page number	1	Screening

Group #	Group Name
1	DM

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Check Box 1	YES	30-MAR-2009 13:09:47 Amanda Lynn	Data Entry Error

Document #: R239713513

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_04 04

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Info_Session	Page number	4	Screening

Group #	Group Name
1	IC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date of Information Session 1	11-MAR-2009 12-MAR-2009	10-JUN-2009 16:51:26 Amanda Lynn	Data Entry Error

Document #: R239713513

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_04 04

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ifc	Page number	4	Screening

Group #	Group Name
1	IC

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date the Subject Signed the Informed Con 1	11-MAR-2009 12-MAR-2009	10-JUN-2009 16:51:26 Amanda Lynn	Data Entry Error

Document #: R239713613

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_05 05

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

Group #	Group Name
1	DM

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Age 1	53 44		10-JUN-2009 16:56:14 Amanda Lynn	Derivation
Date 1	11-MAR-2009 12-MAR-2009		10-JUN-2009 16:55:36 Amanda Lynn	Data Entry Error
Date of Birth 1	24-APR-1955 19-JUL-1964		10-JUN-2009 16:55:36 Amanda Lynn	Data Entry Error
Gender 1	FEMALE MALE		10-JUN-2009 16:55:36 Amanda Lynn	Data Entry Error

Document #: R239713613

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_05 05

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

Group #	Group Name
1	BM

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date 1	11-MAR-2009 12-MAR-2009		22-OCT-2009 14:12:58 Amanda Lynn	Data Entry Error
Height 1	62.1 66.4		10-JUN-2009 16:55:36 Amanda Lynn	Data Entry Error

Document #: R239713713

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_06 06

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Vs	Page number	6	Screening

Group #	Group Name
1	VS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	1002 0910	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error
Body Temperature 1	036.8 36.8	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error
Date 1	11-MAR-2009 12-MAR-2009	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error
Diastolic Blood Pressure 1	090 072	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error
Heart Rate 1	075 058	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error
Respiratory Rate 1	010 12	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error
Systolic Blood Pressure 1	138 120	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error
Weight 1	285.8 210.4	10-JUN-2009 16:56:15 Amanda Lynn	Data Entry Error

Document #: R239713813

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_07 07

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

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	11-MAR-2009 12-MAR-2009	10-JUN-2009 17:04:31 Amanda Lynn	Data Entry Error
Requisition Number 1: (1) 1	070-685-0007-0 071-685-0004-0	22-OCT-2009 14:13:56 Amanda Lynn	Data Entry Error

Document #: R239713813

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_07 07

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

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCM Blank flag 1	Y N	10-JUN-2009 17:04:31 Amanda Lynn	Data Entry Error

Document #: R239713813

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_07 07

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

Group #	Group Name
0	Section Header

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCM Blank flag 1	Y N	10-JUN-2009 17:04:31 Amanda Lynn	Data Entry Error

Document #: R239713913

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_08 08

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eg	Page number	8	Screening

Group #	Group Name
1	EG

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Actual Time 1	0953 0918	10-JUN-2009 17:07:50 Amanda Lynn	Data Entry Error
Date 1	11-MAR-2009 12-MAR-2009	10-JUN-2009 17:07:50 Amanda Lynn	Data Entry Error

Document #: R239714113

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_09 09

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	31-MAR-2009 11:54:57 Amanda Lynn	Data Entry Error
DCI Blank Flag 1	Y N	31-MAR-2009 11:55:11 Amanda Lynn	Data Entry Error

Document #: R239714113

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_09 09

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

Group #	Group Name
1	DTE

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Date 1	11-MAR-2009 12-MAR-2009		22-OCT-2009 14:15:16 Amanda Lynn	Data Entry Error

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Does the subject have any relevant medic 1	NO		31-MAR-2009 11:55:11 Amanda Lynn	Row Inserted

Document #: R241106513

Patient Site	Visit Visit Date	CRF CRF Page
R2005 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 (other attempts) (7) 1	TRIED COLED TURKEY IN JANUARY 1084 AND JULY 2000.	07-MAY-2009 10:07:53 Amanda Lynn	Data Entry Error
Comments (other attempts) (7) 1	TRIED COLED TURKEY IN JANUARY 1084 AND JULY 2000. TRIED COLED TURKEY IN JANUARY 1984 AND JULY 2000.	10-MAR-2010 09:57:25 Amanda Lynn	Data Entry Error
Comments (other attempts) (7) 1	TRIED COLED TURKEY IN JANUARY 1984 AND JULY 2000. TRIED COLD TURKEY IN JANUARY 1984 AND JULY 2000.	10-MAR-2010 11:36:53 Krysia Magnuson	ODM/SEC Coled to cold. KAY 10Mar2010.
If yes, how many (other attempts to quit) (6) 1	3 2	07-MAY-2009 10:07:53 Amanda Lynn	Data Entry Error

Document #: R239716813

Patient Site	Visit Visit Date	CRF CRF Page
R2005 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
Date 1	11-MAR-2009 12-MAR-2009	22-OCT-2009 14:15:49 Amanda Lynn	Data Entry Error
Date 2	11-MAR-2009 12-MAR-2009	22-OCT-2009 14:15:49 Amanda Lynn	Data Entry Error
Findings 2	UPPER AND LOWER DENTURES	22-OCT-2009 14:15:49 Amanda Lynn	Data Entry Error
Findings* 2	YES NO	22-OCT-2009 14:15:49 Amanda Lynn	Data Entry Error
Date 3	11-MAR-2009 12-MAR-2009	22-OCT-2009 14:15:49 Amanda Lynn	Data Entry Error
Findings* 3	NE NO	11-JAN-2010 11:38:42 Amanda Lynn	Data Entry Error

Document #: R239717813

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_12 12

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

Group #	Group Name
1	DTE

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	11-MAR-2009 12-MAR-2009	22-OCT-2009 14:16:53 Amanda Lynn	Data Entry Error

Document #: R239718213

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Screening	Page_13 13

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Behavioral Coun	Page number	13	Screening

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	11-MAR-2009 12-MAR-2009	22-OCT-2009 14:17:13 Amanda Lynn	Data Entry Error
Date 2	11-MAR-2009 12-MAR-2009	22-OCT-2009 14:17:13 Amanda Lynn	Data Entry Error

Document #: R239909613

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Baseline, Week 0	Page_14 14

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Eco	Page number	14	Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
%COHb 1	3.3 3.5	10-JUN-2009 16:52:54 Amanda Lynn	Data Entry Error
Actual Time 1	0835 1144	10-JUN-2009 16:52:54 Amanda Lynn	Data Entry Error
Date 1	23-MAR-2009 24-MAR-2009	10-JUN-2009 16:52:54 Amanda Lynn	Data Entry Error
ECO Level 1	17 8	10-JUN-2009 16:52:54 Amanda Lynn	Data Entry Error

Document #: R239909613

Patient Site	Visit Visit Date	CRF CRF Page	
R2005 L0689282_2	Baseline, Week 0	Page_14 14	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Behavioral Coun	Page number	14	Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	23-MAR-2009 24-MAR-2009	10-JUN-2009 16:52:54 Amanda Lynn	Data Entry Error

Document #: R239909613

Patient Site	Visit Visit Date	CRF CRF Page	
R2005 L0689282_2	Baseline, Week 0	Page_14 14	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Questionnaires	Page number	14	Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	23-MAR-2009 24-MAR-2009	26-FEB-2010 15:27:22 Amanda Lynn	Data Entry Error

Document #: R239909913

Patient Site	Visit Visit Date	CRF CRF Page	
R2005 L0689282_2	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 On resequence By	Reason Comment
Actual Time 1	0850 1213	10-JUN-2009 16:54:32 Amanda Lynn	Data Entry Error
Date 1	23-MAR-2009 24-MAR-2009	10-JUN-2009 16:54:32 Amanda Lynn	Data Entry Error

Document #: R239909913

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Baseline, Week 0	Page_15 15

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Ex	Page number	15	Baseline, Week 0

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
0.5 g of snus or placebo logs dispensed 1	1 8		10-JUN-2009 16:54:32 Amanda Lynn	Data Entry Error
1.0 g of snus or placebo logs dispensed 1	0 4		10-JUN-2009 16:54:32 Amanda Lynn	Data Entry Error
Date 1	23-MAR-2009 24-MAR-2009		10-JUN-2009 16:54:32 Amanda Lynn	Data Entry Error

Document #: R239909913

Patient Site	Visit Visit Date	CRF CRF Page	
R2005 L0689282_2	Baseline, Week 0	Page_15 15	
Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Diary	Page number	15	Baseline, Week 0

Group #	Group Name
1	DRUGSCR

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Date 1	23-MAR-2009 24-MAR-2009	10-JUN-2009 16:54:32 Amanda Lynn	Data Entry Error

Document #: R242095513

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	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
Date 1	07-MAR-2009 07-APR-2009	10-MAR-2010 10:07:59 Amanda Lynn	Data Entry Error

Document #: R242095513

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	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
Date 1	14-MAR-2009 14-APR-2009	10-MAR-2010 10:08:47 Amanda Lynn	Data Entry Error

Document #: R244948713

Patient Site	Visit Visit Date	CRF CRF Page
R2005 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
Comments (how many cigarettes) (5) 1	WAS NOT CAPTURED ON SOURCE.	10-JUN-2009 17:08:56 Amanda Lynn	Data Entry Error
Comments (how many cigarettes) (5) 1	WAS NOT CAPTURED ON SOURCE.	10-JUN-2009 17:53:55 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	UNKKNOWN	10-JUN-2009 17:08:56 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	UNKKNOWN 28	10-JUN-2009 17:53:55 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	28	22-OCT-2009 14:17:41 Amanda Lynn	Data Entry Error
Was Subject compliant (4) 1	YES NO	10-JUN-2009 17:08:56 Amanda Lynn	Data Entry Error
Was Subject compliant (4) 1	NO YES	22-OCT-2009 14:17:41 Amanda Lynn	Data Entry Error

Document #: R239910513

Patient Site	Visit Visit Date	CRF CRF Page
R2005 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	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STERIODS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Dose 1	2 400	24-APR-2009 15:56:06 Amanda Lynn	Data Entry Error
Drug name 1	GENERIC STOOL SOFTENER IBUPROFEN	24-APR-2009 15:56:06 Amanda Lynn	Data Entry Error
Frequency 1	EVERY DAY ONCE	24-APR-2009 15:56:06 Amanda Lynn	Data Entry Error
Indication 1	CONSTIPATION HEADACHE	24-APR-2009 15:56:06 Amanda Lynn	Data Entry Error
Ongoing 1	CHECKED	24-APR-2009 15:56:06 Amanda Lynn	Data Entry Error

Document #: R239910513

Patient Site	Visit Visit Date	CRF CRF Page
R2005 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			
Start Date	09-MAR-2009	24-APR-2009	15:56:06	Data Entry Error
1	21-APR-2009	Amanda Lynn		
Stop Date		24-APR-2009	15:56:06	Data Entry Error
1	21-APR-2009	Amanda Lynn		
Unit	TABLET	24-APR-2009	15:56:06	Data Entry Error
1	MILLIGRAMS	Amanda Lynn		

Document #: R260407913

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Pcm.1	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	J	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC1 Code 1	J	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Code 1	J S	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC1 Text 1	ANTIINFECTIVES FOR SYSTEMIC USE, J	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC1 Text 1	ANTIINFECTIVES FOR SYSTEMIC USE, J	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC1 Text 1	ANTIINFECTIVES FOR SYSTEMIC USE, J SENSORY ORGANS, S	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Code 1	J01	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Code 1	J01	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Code 1	J01 S01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC2 Text 1	ANTIBACTERIALS FOR SYSTEMIC USE, J01	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC2 Text 1	ANTIBACTERIALS FOR SYSTEMIC USE, J01	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC2 Text 1	ANTIBACTERIALS FOR SYSTEMIC USE, J01 OPHTHALMOLOGICALS, S01	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Code 1	J01M	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Code 1	J01M	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change

Document #: R260407913

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Pcm.1	Page_39

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

Group #	Group Name
1	CM1

ATC3 Code 1	J01M S01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC3 Text 1	QUINOLONE ANTIBACTERIALS, J01M	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC3 Text 1	QUINOLONE ANTIBACTERIALS, J01M	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC3 Text 1	QUINOLONE ANTIBACTERIALS, J01M ANTIINFECTIVES, S01A	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Code 1	J01MA	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Code 1	J01MA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Code 1	J01MA S01AX	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
ATC4 Text 1	FLUOROQUINOLONES, J01MA	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
ATC4 Text 1	FLUOROQUINOLONES, J01MA	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
ATC4 Text 1	FLUOROQUINOLONES, J01MA OTHER ANTIINFECTIVES, S01AX	27-APR-2010 12:10:38 Joanne Mccaigue	Class. Change
Drug Modified Reported Term 1	VIGAMOX VIGAMOX 0.5% SOLUTION	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	VIGAMOX VIGAMOX 0.5% SOLUTION	09-APR-2010 15:52:45 Amanda Lynn	Data Entry Error
Frequency 1	EVERY DAY OTHER	29-JUL-2009 14:26:20 Amanda Lynn	Data Entry Error
Indication 1	BACTERIAL CORNEAL ULCER CORNEAL ULCER	22-OCT-2009 14:19:20 Amanda Lynn	Data Entry Error
Preferred Term 1	MOXIFLOXACIN HYDROCHLORIDE	20-APR-2010 11:39:56 Carol Kraucyk	Data Change

Document #: R260407913

Patient Site	Visit Visit Date	CRF CRF Page
R2005 L0689282_2	Pcm.1	Page_39

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

Group #	Group Name
1	CM1

Preferred Term 1	MOXIFLOXACIN HYDROCHLORIDE	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Preferred Term Code 1	01453202001	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Preferred Term Code 1	01453202001	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name 1	VIGAMOX	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Trade Name 1	VIGAMOX	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
Trade Name Code 1	01453202008	20-APR-2010 11:39:56 Carol Kraucyk	Data Change
Trade Name Code 1	01453202008	26-APR-2010 10:36:00 Carol Kraucyk	Class. Change
other, specify (frequency) 1	EVERY 5 HOURS	29-JUL-2009 14:26:20 Amanda Lynn	Data Entry Error
other, specify (unit) 1	DROP 0.5% SOLUTION DROP	09-APR-2010 15:52:45 Amanda Lynn	Data Entry Error

Discrepancy Detail Report

Document #: R239713513

Discrepancy ID: 1670579013

Site: L0689282_2

Patient: R2005

Visit: SCREENING

Visit Date:

CRF: PAGE_04

Section: INFO_SESSION

Qualifying Value: 4

Field:

Row:

Value Text:

Type: MANUAL HEADER

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review ALL screening data - incorrect subject data entered

Internal Comment:

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

Resolution Text:

Document #: R239713613

Discrepancy ID: 1777970713

Site: L0689282_2

Patient: R2005

Visit: SCREENING

Visit Date:

CRF: PAGE_05

Section: BM

Qualifying Value: 5

Field: Date

Row: 1

Value Text: 20090312

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please confirm date.

Internal Comment:

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

Resolution Text:

Document #: R239713813

Discrepancy ID: 1777971913

Site: L0689282_2

Patient: R2005

Visit: SCREENING

Visit Date:

CRF: PAGE_07

Section: LB

Qualifying Value: 7

Field: Requisition Number 1:

Row: 1

Value Text: 071-685-0004-0

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify requisition number.

Internal Comment:

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

Resolution Text:

Document #: R239714113

Discrepancy ID: 1777972013

Site: L0689282_2

Patient: R2005

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Date

Row: 1

Value Text: 20090312

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify date of med. hx.

Internal Comment:

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

Resolution Text:

Document #: R239716813

Discrepancy ID: 1777972313 **Site:** L0689282_2 **Patient:** R2005
Visit: SCREENING **Visit Date:**
CRF: PAGE_11 **Section:** ORAL HEALTH EXA **Qualifying Value:** 11
Field: Date **Row:** 1
Value Text: 20090312
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify dates.

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

Discrepancy ID: 1777972213 **Site:** L0689282_2 **Patient:** R2005
Visit: SCREENING **Visit Date:**
CRF: PAGE_11 **Section:** ORAL HEALTH EXA **Qualifying Value:** 11
Field: Findings **Row:** 2
Value Text:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review entry. Dentures are not the same as cervicies. Please revise responses to yes/no question and delete comment.

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

Discrepancy ID: 36477111 **Site:** L0689282_2 **Patient:** R2005
Visit: SCREENING **Visit Date:**
CRF: PAGE_11 **Section:** ORAL HEALTH EXA **Qualifying Value:** 11
Field: Findings* **Row:** 3
Value Text: NO
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per eNTE this should be marked No instead of NE.

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

Document #: R239717813

Discrepancy ID: 1777972413

Site: L0689282_2

Patient: R2005

Visit: SCREENING

Visit Date:

CRF: PAGE_12

Section: PE

Qualifying Value: 12

Field: Date

Row: 1

Value Text: 20090312

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify date.

Internal Comment:

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

Resolution Text:

Document #: R239718213

Discrepancy ID: 1777972513

Site: L0689282_2

Patient: R2005

Visit: SCREENING

Visit Date:

CRF: PAGE_13

Section: BEHAVIORAL COUN

Qualifying Value: 13

Field: Date

Row: 1

Value Text: 20090312

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify dates.

Internal Comment:

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

Resolution Text:

Document #: R239909613

Discrepancy ID: 1670579313

Site: L0689282_2

Patient: R2005

Visit: BASELINE, WEEK

Visit Date:

CRF: PAGE_14

Section: ECO

Qualifying Value: 14

Field: Date

Row: 1

Value Text: 20090324

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please review all data at week 0 - incorrect subject entered

Internal Comment:

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

Resolution Text:

Document #: R242095513

Discrepancy ID: 79666211

Site: L0689282_2

Patient: R2005

Visit: SPTP, WEEKS 1-4 **Visit Date:**

CRF: PAGE_16

Section: STATUS REVIEW

Qualifying Value: 16A

Field: Date

Row: 1

Value Text: 20090414

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify updating date to 14-APR-2009 as 14-MAR-2009 is prior to randomization date.

Internal Comment:

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

Resolution Text:

Document #: R244948713

Discrepancy ID: 1670580013 **Site:** L0689282_2 **Patient:** R2005
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:
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Per return questionnaire and diary, subject did not smoke any during week 6. Please review and revise response to yes/no question and amount.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 1670579913 **Site:** L0689282_2 **Patient:** R2005
Visit: IP, WEEK 6 **Visit Date:**
CRF: PAGE_20 **Section:** STATUS REVIEW **Qualifying Value:** 20
Field: Was Subject compliant **Row:** 1
Value Text: YES
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please review response. Subject smoked during week 5
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Document #: R260407913

Discrepancy ID: 1778025013 **Site:** L0689282_2 **Patient:** R2005
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: Indication **Row:** 1
Value Text: CORNEAL ULCER
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Indication should match the AE of Corneal ulcer.
Internal Comment:
Resolution Type: Data value changed. Disc no longer applicable.
Resolution Text:

Discrepancy ID: 98517911 **Site:** L0689282_2 **Patient:** R2005
Visit: PCM.1 **Visit Date:**
CRF: PAGE_39 **Section:** PCM **Qualifying Value:** 39
Field: other, specify (unit) **Row:** 1
Value Text: DROP
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please update unit to 'drop.' If 0.5% solution is wanted, please add to drug name.
Internal Comment:
Resolution Type: Confirmed
Resolution Text: Verified. JLM 20Apr2010

Deleted CRFs Report