

CRF Report for Study E7694105

Report run by Brian Saari at 06-MAR-2013 13:56:46

Report Parameters

Site: CP_001

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R3025

Ending patient: R3025

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

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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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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="06-MAY-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="63.3"/>

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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	078
Heart Rate	BEATS/MINUTE	077
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.4
Weight	LB	246.8

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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Safety Urine & Blood Tests; Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Urine Pregnancy Test

Result

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

Urine Drug Screen

Drug Screen Result*

Positive Negative

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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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="06-MAY-2009"/>	<input type="text" value="13:21"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal Abnormal, NCS Abnormal, CS

Comments Regarding CS Findings:

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Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Medical History

Date

Does the subject have any relevant medical history? Yes No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	NASAL/SINUS CONGESTION-OCCASIONAL ALL	00-00-1993		<input checked="" type="checkbox"/> Ongoing
2	POLYCYSTIC OVARIAN SYNDROME	00-00-2003		<input checked="" type="checkbox"/> Ongoing
3	HOT FLASHES	00-MAR-2009		<input checked="" type="checkbox"/> Ongoing
4	MIGRAINES-DUE TO CAFFEINE WITHDRAWAL	00-00-2001		<input checked="" type="checkbox"/> Ongoing
5	DIZZINESS/LIGHTHEADEDNESS DUE TO LOW	00-00-1998		<input checked="" type="checkbox"/> Ongoing
6	PUMPKIN ALLERGY	00-00-1978		<input checked="" type="checkbox"/> Ongoing
7	SEASONAL ALLERGIES	00-00-1984		<input checked="" type="checkbox"/> Ongoing
8	MENSTRUAL PAIN	00-00-1984		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

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

Document Number

OverFlow Section For Document Number R250260513

- 1 NASAL/SINUS CONGESTION-OCCASIONAL ALLERGIES
- 2 DIZZINESS/LIGHTHEADEDNESS DUE TO LOW BLOOD SUGAR

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="13"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="15"/>	
Has subject used smokeless tobacco in the past?	<input 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	NICOTINE PATCH, ONCE
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 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 other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many times? <input type="text" value="1"/>	NO AIDE, ONCE

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

Behavioral Counseling

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

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
12-MAY-2009	11:08	020	03.8	

Behavioral Counseling

Date	Parameter	Result	Comments
12-MAY-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="4"/> logs
1.0 g of snus or matching placebo	<input type="text" value="2"/> logs

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="19-MAY-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="42"/>	<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="26-MAY-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="40"/>	<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="03-JUN-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="30"/>	<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

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="20"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject reminded about the complete switch from cigarettes no later than the first day of Week 5?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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

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	106
Diastolic Blood Pressure	MMHG	073
Heart Rate	BEATS/MINUTE	078
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.7
Weight	LB	245.2

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Page Version No. PAGE_17 (v1, 30-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.

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
24-JUN-2009	10:42	8	1.9	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire MNWS Was Questionnaire Administered? Yes No

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Product Dispensation

Date

Product

Amount Dispensed

0.5 g of snus or matching placebo 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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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="10-JUL-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="3"/>	<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)

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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		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

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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
<input type="text"/>				

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?
MNWS Yes No

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

Status Review

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

Diary Distribution

Date Did subject receive diary and usage instructions?
 Yes No

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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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Status Review

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

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	122
Diastolic Blood Pressure	MMHG	080
Heart Rate	BEATS/MINUTE	077
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	36.6
Weight	LB	246.2

Verified Approved Locked Frozen

Page Version No. PAGE_26 (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_27 (v1, 25-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
04-AUG-2009	10:06	17	3.3	

Behavioral Counseling

Date	Parameter	Result	Comments
04-AUG-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
04-AUG-2009	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="UNK"/>	EXACT AMOUNT UNKNOWN, PEI
	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

OverFlow Section For Document Number R275215713

1 EXACT AMOUNT UNKNOWN, PER FAGERSTROM TEST IT IS 10 OR LESS PER DAY

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

Status Review

Date Scheduled Timepoint

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

Date Scheduled Timepoint

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

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

Behavioral Counseling

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

Questionnaires

Date

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

Verified Approved Locked Frozen

Page Version No. PAGE_37 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below. No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

Verified Approved Locked Frozen

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

Document Number

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[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)

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events? Yes No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time Ongoing

Serious Event: Select only one
 Yes
 No

Severity: Select only one
 Mild
 Moderate
 Severe

Relationship Select only one
to Date: Not Related
 Unlikely
 Possibly Related
 Probably Related
 Definitely Related

Action Taken: Select only one
 None
 Other Drug Therapy, Specify as Con. Med.
 Other Treatment or Procedure, Specify:

 Discontinuation from Study
 Discontinuation of Drug Therapy

Outcome to Date Select only one
 Recovered
 Continuing without Treatment
 Continuing with Treatment
 Death

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 12-Lead Electrocardiogram Report

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

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

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Laboratory Evaluations

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

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

Note: Attach copy of signed laboratory report.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - Vital Signs

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

Date Actual Time

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

Comments

Date Actual Time

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

Comments

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

* Indicate NE if system was not examined.

Verified Approved Locked Frozen

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

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Study Completion

Date the subject completed OR withdrew from the study:

Reason for Withdrawal (check one):

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

Investigator Comments (if none, leave blank):

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

Verified Approved Locked Frozen

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

Document Number

Links to Discrepancy and Audit Sections

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

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

Appendix: Audit and Discrepancy Information

Audit History Report

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

Document #: R250260513

Patient Site	Visit Visit Date	CRF CRF Page
R3025	Screening	Page_09
CP_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 resequence	On By	Reason Comment
Date of Onset 1	00-00-1993		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Resolution 1			27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION- OCCASIONAL ALLERGIES		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Does the subject have any relevant medication 1	NO YES		27-AUG-2009 20:40:16 Tricia Hunt	Data Entry Error
Ongoing 1	CHECKED		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Sequence Number 1	1		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Onset 2	00-00-2003		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Resolution 2			27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Diagnosis/Procedure 2	POLYCYSTIC OVARIAN SYNDROME		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Ongoing 2	CHECKED		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Sequence Number 2	2		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Onset 3	00-00-2003		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Onset 3	00-00-2003		23-NOV-2009 13:05:13 Marilyn Mindolovich	Data Entry Error
Date of Onset 3	<Row Deleted>		11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error

Document #: R250260513

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Date of Onset		11-FEB-2010 13:44:28	Row Inserted
3	00-MAR-2009	Tricia Hunt	
Date of Resolution		27-AUG-2009 20:40:16	Row Inserted
3		Tricia Hunt	
Date of Resolution		11-FEB-2010 13:44:28	Data Entry Error
3	<Row Deleted>	Tricia Hunt	
Date of Resolution		11-FEB-2010 13:44:28	Row Inserted
3		Tricia Hunt	
Diagnosis/Procedure		27-AUG-2009 20:40:16	Row Inserted
3	OVARIAN CYST OR MASS DUE TO PCOS	Tricia Hunt	
Diagnosis/Procedure		23-NOV-2009 13:05:13	Investigator Correction
3	OVARIAN CYST OR MASS DUE TO PCOS	Marilyn Mindolovich	
Diagnosis/Procedure		11-FEB-2010 13:44:28	Data Entry Error
3	<Row Deleted>	Tricia Hunt	
Diagnosis/Procedure		11-FEB-2010 13:44:28	Row Inserted
3	HOT FLASHES	Tricia Hunt	
Ongoing		27-AUG-2009 20:40:16	Row Inserted
3	CHECKED	Tricia Hunt	
Ongoing		23-NOV-2009 13:05:13	Data Entry Error
3	CHECKED	Marilyn Mindolovich	
Ongoing		11-FEB-2010 13:44:28	Data Entry Error
3	<Row Deleted>	Tricia Hunt	
Ongoing		11-FEB-2010 13:44:28	Row Inserted
3	CHECKED	Tricia Hunt	
Sequence Number		27-AUG-2009 20:40:16	Row Inserted
3	3	Tricia Hunt	
Sequence Number		11-FEB-2010 13:44:28	Data Entry Error
3	<Row Deleted>	Tricia Hunt	
Sequence Number		11-FEB-2010 13:44:28	Row Inserted
3	3	Tricia Hunt	

Document #: R250260513

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Date of Onset 4	00-MAR-2009	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Onset 4	00-MAR-2009 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Date of Onset 4	00-00-2001	11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Date of Resolution 4		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Resolution 4	<Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Date of Resolution 4		11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Diagnosis/Procedure 4	HOT FLASHES	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Diagnosis/Procedure 4	HOT FLASHES <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Diagnosis/Procedure 4	MIGRAINES-DUE TO CAFFINE WITHDRAWAL	11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Diagnosis/Procedure 4	MIGRAINES-DUE TO CAFFINE WITHDRAWAL MIGRAINES-DUE TO CAFFEINE WITHDRAWAL	16-MAR-2010 15:10:01 Kryisia Magnuson	ODM/SEC Caffine to Caffeine. KAY 16Mar2010.
Ongoing 4	CHECKED	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Ongoing 4	CHECKED <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Ongoing 4	CHECKED	11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Sequence Number 4	4	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Sequence Number 4	4 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error

Document #: R250260513

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_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		11-FEB-2010 13:44:28	Row Inserted
4	4	Tricia Hunt	
Date of Onset		27-AUG-2009 20:40:16	Row Inserted
5	00-00-2003	Tricia Hunt	
Date of Onset		23-NOV-2009 13:05:13	Data Entry Error
5	00-00-2003	Marilyn Mindolovich	
Date of Onset		11-FEB-2010 13:44:28	Data Entry Error
5	<Row Deleted>	Tricia Hunt	
Date of Onset		11-FEB-2010 13:44:28	Row Inserted
5	00-00-1998	Tricia Hunt	
Date of Resolution		27-AUG-2009 20:40:16	Row Inserted
5		Tricia Hunt	
Date of Resolution		11-FEB-2010 13:44:28	Data Entry Error
5	<Row Deleted>	Tricia Hunt	
Date of Resolution		11-FEB-2010 13:44:28	Row Inserted
5		Tricia Hunt	
Diagnosis/Procedure		27-AUG-2009 20:40:16	Row Inserted
5	POLYCYSTIC OVARY	Tricia Hunt	
Diagnosis/Procedure		23-NOV-2009 13:05:13	Data Entry Error
5	POLYCYSTIC OVARY	Marilyn Mindolovich	
Diagnosis/Procedure		11-FEB-2010 13:44:28	Data Entry Error
5	<Row Deleted>	Tricia Hunt	
Diagnosis/Procedure		11-FEB-2010 13:44:28	Row Inserted
5	DIZZINESS/LIGHTHEADEDNESS DUE TO LOW BLOOD SUGAR	Tricia Hunt	
Ongoing		27-AUG-2009 20:40:16	Row Inserted
5	CHECKED	Tricia Hunt	
Ongoing		23-NOV-2009 13:05:13	Data Entry Error
5	CHECKED	Marilyn Mindolovich	
Ongoing		11-FEB-2010 13:44:28	Data Entry Error
5	<Row Deleted>	Tricia Hunt	

Document #: R250260513

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Screening	Page_09 09

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
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Group #	Group Name
2	MH1

Ongoing		11-FEB-2010 13:44:28	Row Inserted
5	CHECKED	Tricia Hunt	
Sequence Number		27-AUG-2009 20:40:16	Row Inserted
5	5	Tricia Hunt	
Sequence Number	5	11-FEB-2010 13:44:28	Data Entry Error
5	<Row Deleted>	Tricia Hunt	
Sequence Number		11-FEB-2010 13:44:28	Row Inserted
5	5	Tricia Hunt	
Date of Onset		27-AUG-2009 20:40:16	Row Inserted
6	00-00-2001	Tricia Hunt	
Date of Onset	00-00-2001	11-FEB-2010 13:44:28	Data Entry Error
6	<Row Deleted>	Tricia Hunt	
Date of Onset		11-FEB-2010 13:44:28	Row Inserted
6	00-00-1978	Tricia Hunt	
Date of Resolution		27-AUG-2009 20:40:16	Row Inserted
6		Tricia Hunt	
Date of Resolution		11-FEB-2010 13:44:28	Data Entry Error
6	<Row Deleted>	Tricia Hunt	
Date of Resolution		11-FEB-2010 13:44:28	Row Inserted
6		Tricia Hunt	
Diagnosis/Procedure		27-AUG-2009 20:40:16	Row Inserted
6	MIGRAINES-DUE TO CAFFINE WITHDRAWL	Tricia Hunt	
Diagnosis/Procedure	MIGRAINES-DUE TO CAFFINE WITHDRAWL	16-NOV-2009 14:43:54	Investigator Correction
6	MIGRAINES-DUE TO CAFFINE WITHDRAWAL	Marilyn Mindolovich	
Diagnosis/Procedure	MIGRAINES-DUE TO CAFFINE WITHDRAWAL	11-FEB-2010 13:44:28	Data Entry Error
6	<Row Deleted>	Tricia Hunt	
Diagnosis/Procedure		11-FEB-2010 13:44:28	Row Inserted
6	PUMPKIN ALLERGY	Tricia Hunt	
Ongoing		27-AUG-2009 20:40:16	Row Inserted
6	CHECKED	Tricia Hunt	

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Patient Site	Visit Visit Date	CRF CRF Page
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Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Mh	Page number	9	Screening

Group #	Group Name			
2	MH1			
Ongoing 6	CHECKED <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt		Data Entry Error
Ongoing 6	CHECKED	11-FEB-2010 13:44:28 Tricia Hunt		Row Inserted
Sequence Number 6	6	27-AUG-2009 20:40:16 Tricia Hunt		Row Inserted
Sequence Number 6	6 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt		Data Entry Error
Sequence Number 6	6	11-FEB-2010 13:44:28 Tricia Hunt		Row Inserted
Date of Onset 7	00-00-1998	27-AUG-2009 20:40:16 Tricia Hunt		Row Inserted
Date of Onset 7	00-00-1998 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt		Data Entry Error
Date of Onset 7	00-00-1984	11-FEB-2010 13:44:28 Tricia Hunt		Row Inserted
Date of Resolution 7		27-AUG-2009 20:40:16 Tricia Hunt		Row Inserted
Date of Resolution 7	<Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt		Data Entry Error
Date of Resolution 7		11-FEB-2010 13:44:28 Tricia Hunt		Row Inserted
Diagnosis/Procedure 7	DIZZINESS/LIGHTHEADEDNES S DUE TO LOW BLOOD SUGAR	27-AUG-2009 20:40:16 Tricia Hunt		Row Inserted
Diagnosis/Procedure 7	DIZZINESS/LIGHTHEADEDNES S DUE TO LOW BLOOD SUGAR <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt		Data Entry Error
Diagnosis/Procedure 7	SEASONAL ALLERGIES	11-FEB-2010 13:44:28 Tricia Hunt		Row Inserted
Ongoing 7	CHECKED	27-AUG-2009 20:40:16 Tricia Hunt		Row Inserted

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Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Ongoing 7	CHECKED <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Ongoing 7	CHECKED	11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Sequence Number 7	7	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Sequence Number 7	7 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Sequence Number 7	7	11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Date of Onset 8	00-00-1978	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Onset 8	00-00-1978 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Date of Onset 8	00-00-1984	11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Date of Resolution 8		27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Date of Resolution 8	<Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Date of Resolution 8		11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Diagnosis/Procedure 8	PUMPKIN ALLERGY	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted
Diagnosis/Procedure 8	PUMPKIN ALLERGY <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Diagnosis/Procedure 8	MENSTRUAL PAIN	11-FEB-2010 13:44:28 Tricia Hunt	Row Inserted
Ongoing 8	CHECKED	27-AUG-2009 20:40:16 Tricia Hunt	Row Inserted

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CP_001		09

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

Group #	Group Name			
2	MH1			
Ongoing	CHECKED	11-FEB-2010	13:44:28	Data Entry Error
8	<Row Deleted>	Tricia Hunt		
Ongoing		11-FEB-2010	13:44:28	Row Inserted
8	CHECKED	Tricia Hunt		
Sequence Number		27-AUG-2009	20:40:16	Row Inserted
8	8	Tricia Hunt		
Sequence Number	8	11-FEB-2010	13:44:28	Data Entry Error
8	<Row Deleted>	Tricia Hunt		
Sequence Number		11-FEB-2010	13:44:28	Row Inserted
8	8	Tricia Hunt		
Date of Onset		27-AUG-2009	20:40:16	Row Inserted
9	00-00-1986	Tricia Hunt		
Date of Onset	00-00-1986	11-FEB-2010	13:44:28	Data Entry Error
9	<Row Deleted>	Tricia Hunt		
Date of Resolution		27-AUG-2009	20:40:16	Row Inserted
9		Tricia Hunt		
Date of Resolution		11-FEB-2010	13:44:28	Data Entry Error
9	<Row Deleted>	Tricia Hunt		
Diagnosis/Procedure		27-AUG-2009	20:40:16	Row Inserted
9	SEASONAL ALLERGIES	Tricia Hunt		
Diagnosis/Procedure	SEASONAL ALLERGIES	11-FEB-2010	13:44:28	Data Entry Error
9	<Row Deleted>	Tricia Hunt		
Ongoing		27-AUG-2009	20:40:16	Row Inserted
9	CHECKED	Tricia Hunt		
Ongoing	CHECKED	11-FEB-2010	13:44:28	Data Entry Error
9	<Row Deleted>	Tricia Hunt		
Sequence Number		27-AUG-2009	20:40:16	Row Inserted
9	9	Tricia Hunt		
Sequence Number	9	11-FEB-2010	13:44:28	Data Entry Error
9	<Row Deleted>	Tricia Hunt		
Date of Onset		16-NOV-2009	13:22:08	Row Inserted
10		Diane Yann		

Document #: R250260513

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Date of Onset 10	00-00-1984	17-NOV-2009 16:08:57 Marilyn Mindolovich	Investigator Correction
Date of Onset 10	00-00-1984 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Date of Resolution 10		16-NOV-2009 13:22:08 Diane Yann	Row Inserted
Date of Resolution 10	<Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Diagnosis/Procedure 10		16-NOV-2009 13:22:08 Diane Yann	Row Inserted
Diagnosis/Procedure 10	MENSTRUAL PAIN	17-NOV-2009 16:08:57 Marilyn Mindolovich	Investigator Correction
Diagnosis/Procedure 10	MENSTRUAL PAIN <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Ongoing 10		16-NOV-2009 13:22:08 Diane Yann	Row Inserted
Ongoing 10	CHECKED	17-NOV-2009 16:08:57 Marilyn Mindolovich	Investigator Correction
Ongoing 10	CHECKED <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error
Sequence Number 10		16-NOV-2009 13:22:08 Diane Yann	Row Inserted
Sequence Number 10	10	17-NOV-2009 16:08:57 Marilyn Mindolovich	Investigator Correction
Sequence Number 10	10 <Row Deleted>	11-FEB-2010 13:44:28 Tricia Hunt	Data Entry Error

Document #: R250261613

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Screening	Page_12 12

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

Group #	Group Name
2	MH1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Does the subject have any abnormal findi 1	YES NO	27-AUG-2009 20:49:09 Tricia Hunt	Data Entry Error
Findings 1	MULTIPLE SURGICAL SCARS FROM PREVOIUS GUNSHOT WOUND <Row Deleted>	27-AUG-2009 20:49:09 Tricia Hunt	Data Entry Error
Sequence Number 1	01 <Row Deleted>	27-AUG-2009 20:49:09 Tricia Hunt	Data Entry Error

Document #: R275214713

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Ip, Week 16	Page_28 28

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Oral Health Exam	Page number	28	Ip, Week 16

Group #	Group Name
1	EX1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Findings* 3	NE NO	16-NOV-2009 14:48:34 Marilyn Mindolovich	Investigator Correction

Document #: R275215713

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Ip, Week 16	Page_31 31

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Status Review	Page number	31	Ip, Week 16

Group #	Group Name
1	CHKYN

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Comments (how many cigarettes) (5) 1	EXAXT AMOUNT UNKNOWN, PER FAGERSTROM TEST IT IS 10 OR LESS PER DAY EXACT AMOUNT UNKNOWN, PER FAGERSTROM TEST IT IS 10 OR LESS PER DAY	16-NOV-2009 14:49:08 Marilyn Mindolovich	Investigator Correction

Document #: R253125613

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Pcm.1	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	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

Document #: R253125713

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Pcm.2	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.2

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	A N	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	ALIMENTARY TRACT AND METABOLISM, A NERVOUS SYSTEM, N	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	A01 N02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	STOMATOLOGICAL PREPARATIONS, A01 ANALGESICS, N02	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	A01A N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	STOMATOLOGICAL PREPARATIONS, A01A OTHER ANALGESICS AND ANTIPYRETICS, N02B	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	A01AD N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Text 1	OTHER AGENTS FOR LOCAL ORAL TREATMENT, A01AD SALICYLIC ACID AND DERIVATIVES, N02BA	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change

Document #: R253125813

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Pcm.3	Page_39

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

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	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

Document #: R275216813

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_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	DYSATHEsia DYSESTHEsia	21-APR-2010 11:28:59 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 21Apr2010
High Level Group Term 1	NEUROLOGICAL DISORDERS NEC	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
High Level Group Term Code 1	10029305	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
High Level Term 1	PARAESTHESIAS AND DYSAESTHESIAS	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
High Level Term Code 1	10033788	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Lower Level Term 1	DYSESTHEsia	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Lower Level Term Code 1	10062872	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Preferred Term 1	DYSAESTHESIA	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Preferred Term Code 1	10013886	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
System Organ Class 1	NERVOUS SYSTEM DISORDERS	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
System Organ Class Code 1	10029205	26-APR-2010 10:42:01 Carol Kraucyk	Data Change
Verbatim Term 1	DYSATHEsia DYSESTHEsia	26-APR-2010 10:36:00 Carol Kraucyk	Data Change

Document #: R280087613

Patient Site	Visit Visit Date	CRF CRF Page
R3025 CP_001	Study Competition	Page_46 46

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

Group #	Group Name
1	DS

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
AE specify 1	DYSATHESIA	30-MAR-2010 12:30:24 Tricia Hunt	Data Entry Error
AE specify 1	DYSATHESIA DYSESTHESIA	21-APR-2010 11:56:38 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 21Apr2010
Other specify (2) 1	COMPLIANCE	11-FEB-2010 14:13:08 Tricia Hunt	Data Entry Error
Reason for withdrawal 1	OTHER WITHDRAWN	23-NOV-2009 13:17:20 Marilyn Mindolovich	Investigator Correction
Reason for withdrawal 1	WITHDRAWN AE	30-MAR-2010 12:30:24 Tricia Hunt	Data Entry Error

Discrepancy Detail Report

Document #: R250260513

Discrepancy ID: 76428811 Site: CP_001 Patient: R3025

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Diagnosis/Procedure

Row: 5

Value Text: DIZZINESS/LIGHTHEADEDNESS DUE TO LOW BLOOD SUGAR

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please update diagnosis/procedure term to indicate if this is episodic/intermittent or a chronic/ongoing condition.

Internal Comment: Please verify change. The Medical History states due to low blood sugar, and is marked as ongoing. Unclear of the change required.

Resolution Type: No Action Required

Resolution Text:

Discrepancy ID: 1683159113 Site: CP_001 Patient: R3025

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Does the subject have any relevant medic

Row: 1

Value Text: YES

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify, per NTF, relevant Med. Hx is any condition that is ongoing. Please review source medical hx information and enter according to the NTF.

Internal Comment:

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

Resolution Text:

Discrepancy ID: 86024611 Site: CP_001 Patient: R3025

Visit: SCREENING

Visit Date:

CRF: PAGE_09

Section: MH

Qualifying Value: 9

Field: Ongoing

Row: 4

Value Text: CHECKED

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify if this is an ongoing condition.

Internal Comment: Per medical history this condition is ongoing.

Resolution Type: Confirmed

Resolution Text:

Document #: R275214713

Discrepancy ID: 1793187513

Site: CP_001

Patient: R3025

Visit: IP, WEEK 16

Visit Date:

CRF: PAGE_28

Section: ORAL HEALTH EXA

Qualifying Value: 28

Field: Findings*

Row: 3

Value Text: NO

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Per eNTF, other oral keratosis should be marked No unless the second page of the PE source has an entry regarding other keratosis.

Internal Comment:

Resolution Type: Confirmed

Resolution Text:

Document #: R275215713

Discrepancy ID: 1793187713 **Site:** CP_001 **Patient:** R3025
Visit: IP, WEEK 16 **Visit Date:**
CRF: PAGE_31 **Section:** STATUS REVIEW **Qualifying Value:** 31
Field: Comments (how many cigarettes) **Row:** 1
Value Text: EXACT AMOUNT UNKNOWN, PER FAGERSTROM TEST IT IS 10 OR LESS PER DAY
Type: MANUAL **Status:** CURRENT
Review Status: Resolved-Response Edited
Discrepancy: Please verify spelling of exact.
Internal Comment:
Resolution Type: Confirmed
Resolution Text:

Document #: R253125513

Discrepancy ID: 1683159413

Site: CP_001

Patient: R3025

Visit: PCM

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: POLYCYSTIC OVARY SYNDROME

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please verify if medical conditions that require con-medications need to listed on Medical hx CRF page as relevant history.

Internal Comment: added to med hx

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

Resolution Text:

Document #: R253125613

Discrepancy ID: 1793188613

Site: CP_001

Patient: R3025

Visit: PCM.1

Visit Date:

CRF: PAGE_39

Section: PCM

Qualifying Value: 39

Field: Indication

Row: 1

Value Text: MENSTRUAL PAIN

Type: MANUAL

Status: CURRENT

Review Status: Resolved-Response Edited

Discrepancy: Please see query left on page 9, med. hx CRF regarding meds taken for menstrual pain (midol and motrin).

Internal Comment:

Resolution Type: No Action Required

Resolution Text:

Document #: R280087613

Discrepancy ID: 1796617513 **Site:** CP_001 **Patient:** R3025
Visit: STUDY COMPETITION **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: Per source progress notes dated 29Jul09, it appears the subject withdrew consent. Please verify.

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

Deleted CRFs Report