

# CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 15:13:07

## Report Parameters

Site: L0689282\_2

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R2010

Ending patient: R2010

### Legend: How different values appear in the report

Prompt	Abc 123
Data value	Abc 123
Data value with discrepancy	<b>Abc 123</b>

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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Swedish Match AB

Protocol Number: SM 08-01

Subject Number

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Subject Initials

Visit Name

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Exclusion Criteria

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

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

\* If Yes, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

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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

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Visit Name

Subject Number

Subject Initials

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Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="09-APR-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="065.5"/>

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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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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	133
Diastolic Blood Pressure	MMHG	072
Heart Rate	BEATS/MINUTE	079
Respiratory Rate	BREATHS/MINUTE	14
Body Temperature	C	36.7
Weight	LB	279.4

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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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Protocol Number: SM 08-01

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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="09-APR-2009"/>	<input type="text" value="10:29"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

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Visit Name

Subject Number

Subject Initials

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Medical History

Date

Does the subject have any relevant medical history?  Yes  No

Sequence

No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
01	NASAL/SINUS CONGESTION EPISODIC/INTER	00-00-1971		<input checked="" type="checkbox"/> Ongoing
02	HIGH BLOOD PRESSURE	00-00-1994		<input checked="" type="checkbox"/> Ongoing
03	INCREASED HEART RATE	00-00-2006		<input checked="" type="checkbox"/> Ongoing
04	SHORTNESS OF BREATH WHEN WALKING	00-00-2000		<input checked="" type="checkbox"/> Ongoing
05	RESPIRATORY BRONCHIAL INTERSTITIAL	00-00-2000		<input checked="" type="checkbox"/> Ongoing
06	DIABETES TYPE II	00-00-1995		<input checked="" type="checkbox"/> Ongoing
07	HEARTBURN	00-00-1985		<input checked="" type="checkbox"/> Ongoing
08	GASTROESOPHAGEAL REFLUX DISEASE	00-00-1985		<input checked="" type="checkbox"/> Ongoing
09	ANEMIA	00-00-1981		<input checked="" type="checkbox"/> Ongoing
10	SEASONAL ALLERGIES	00-00-1999		<input checked="" type="checkbox"/> Ongoing
11	DIABETIC NEUROPATHY	00-FEB-2004		<input checked="" type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

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Document Number

## OverFlow Section For Document Number R243911113

1 NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT

## **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="16"/>	
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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? List details of NRT products used in COMMENTS section.	<input 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="2"/>	CHANTIX ONCE 2008 AND WELLBUTRIN ONCE 2007
Has the subject attempted to quit with the use of other smoking cessation aids? List details of other smoking cessation aids used in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	
Has the subject made any other attempts to quit smoking? List details of other quit attempts in the COMMENTS section.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, how many times? <input type="text"/>	

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Document Number

## OverFlow Section For Document Number R243394013

1 CHANTIX ONCE 2008 AND WELLBUTRIN ONCE 2007

## **Links to Discrepancy and Audit Sections**

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

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Visit Name

Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

Date	Parameter	Result	Comments
09-APR-2009	WAS BEHAVIORAL COUNSELING GIVEN?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
09-APR-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
22-APR-2009	10:08	26	4.7	

Behavioral Counseling

Date	Parameter	Result	Comments
22-APR-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="10"/> logs
1.0 g of snus or matching placebo	<input type="text" value="6"/> 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

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Subject Initials

Visit Name

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="29-APR-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="70"/>	<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="06-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="49"/>	<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="13-MAY-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="49"/>	<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
<input type="text" value="20-MAY-2009"/>	<input type="text" value="WEEK 4"/>	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="35"/>	<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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## **Links to Discrepancy and Audit Sections**

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	114
Diastolic Blood Pressure	MMHG	070
Heart Rate	BEATS/MINUTE	092
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	36.7
Weight	LB	279.6

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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"/>
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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
02-JUN-2009	08:07	7	1.7	

Behavioral Counseling

Date	Parameter	Result	Comments
02-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

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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="02-JUN-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="21"/>	<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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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="18-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 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="14"/>	<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	114
Diastolic Blood Pressure	MMHG	065
Heart Rate	BEATS/MINUTE	104
Respiratory Rate	BREATHS/MINUTE	22
Body Temperature	C	37.0
Weight	LB	278.6

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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
01-JUL-2009	10:15	16	3.1	

Behavioral Counseling

Date	Parameter	Result	Comments
01-JUL-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="5"/> logs
1.0 g of snus or matching placebo	<input type="text" value="0"/> logs

Status Review

Date	Parameter	Result	Comments
<input type="text" value="01-JUL-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="21"/>	<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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## **Links to Discrepancy and Audit Sections**

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="22-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="21"/>	<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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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	105
Diastolic Blood Pressure	MMHG	066
Heart Rate	BEATS/MINUTE	104
Respiratory Rate	BREATHS/MINUTE	18
Body Temperature	C	36.7
Weight	LB	281.6

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

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

Oral Health Examination

Date	Procedure	Findings*	Findings
12-AUG-2009	EVIDENCE OF LEUKOPLAKIA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
12-AUG-2009	EXPOSED DENTAL SERVICES IN UPPER SULCUS?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NE	
12-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.

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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
12-AUG-2009	10:19	21	3.9	

Behavioral Counseling

Date	Parameter	Result	Comments
12-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

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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="12-AUG-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="14"/>	<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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Document Number

## **Links to Discrepancy and Audit Sections**

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date  Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="14"/>	<input type="text"/>
Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Date  Scheduled Timepoint

Parameter	Result	Comments
Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="112"/>	<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 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	122
Diastolic Blood Pressure	MMHG	078
Heart Rate	BEATS/MINUTE	102
Respiratory Rate	BREATHS/MINUTE	22
Body Temperature	C	36.7
Weight	LB	280.4

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

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

Oral Health Examination

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

\* Indicate NE if system was not examined.

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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
04-NOV-2009	10:25	9	2.0	

Behavioral Counseling

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

Questionnaires

Date

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

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Document Number

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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="04-NOV-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="28"/>	<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

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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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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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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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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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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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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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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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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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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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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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.

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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

Additional Assessments - Vital Signs

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

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	ND
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	ND
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	102
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	ND
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	ND
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	100
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

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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

Additional Assessments - Vital Signs

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

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	ND
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	ND
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	098
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Date  Actual Time

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

Comments

Verified  Approved  Locked  Frozen

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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

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

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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

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 #: R243911113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Screening	Page_09 09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	9	Screening

<b>Group #</b>	<b>Group Name</b>
2	MH1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date of Onset 1	00-00-1971	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Date of Resolution 1		11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT	03-MAR-2010 11:59:13 Amanda Lynn	Data Entry Error
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT NASAL/SINUS CONGESTION	03-MAR-2010 12:06:01 Amanda Lynn	Data Entry Error
Diagnosis/Procedure 1	NASAL/SINUS CONGESTION NASAL/SINUS CONGESTION EPISODIC/INTERMITTENT	03-MAR-2010 12:16:35 Amanda Lynn	Data Entry Error
Does the subject have any relevant medication 1	NO YES	11-JUN-2009 14:39:10 Amanda Lynn	Data Entry Error
Ongoing 1	CHECKED	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Sequence Number 1	01	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Date of Onset 2	00-00-1994	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Date of Resolution 2		11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Diagnosis/Procedure 2	HIGH BLOOD PRESSURE	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Ongoing 2	CHECKED	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted

Document #: R243911113

Patient Site	Visit Visit Date	CRF CRF Page
R2010 L0689282_2	Screening	Page_09 09

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

Group #	Group Name
2	MH1

Sequence Number	2	11-JUN-2009 14:39:10	Row Inserted
Date of Onset	00-00-2006	11-JUN-2009 14:39:10	Row Inserted
Date of Resolution		11-JUN-2009 14:39:10	Row Inserted
Diagnosis/Procedure	INCREASED HEART RATE	11-JUN-2009 14:39:10	Row Inserted
Ongoing	CHECKED	11-JUN-2009 14:39:10	Row Inserted
Sequence Number	03	11-JUN-2009 14:39:10	Row Inserted
Date of Onset	00-00-2000	11-JUN-2009 14:39:10	Row Inserted
Date of Resolution		11-JUN-2009 14:39:10	Row Inserted
Diagnosis/Procedure	SHORTNESS OF BREATH WHEN WALKING	11-JUN-2009 14:39:10	Row Inserted
Ongoing	CHECKED	11-JUN-2009 14:39:10	Row Inserted
Sequence Number	04	11-JUN-2009 14:39:10	Row Inserted
Date of Onset	00-00-2000	11-JUN-2009 14:39:10	Row Inserted
Date of Onset	00-00-2000	10-MAR-2010 09:58:32	Data Entry Error
Date of Onset	<Row Deleted>	12-24-MAR-2010 15:31:59	Data Entry Error

Document #: R243911113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Screening	Page_09 09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	9	Screening

<b>Group #</b>	<b>Group Name</b>
2	MH1

Date of Resolution 5		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Date of Resolution 5	<Row Deleted>	12- >11;11- >10;10- >9;9- >8;8- >7;7- >6;6->5	24-MAR-2010 15:31:59 Data Entry Error Kryisia Magnuson
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Diagnosis/Procedure 5	SHORTNESS OF BREATH UPON EXERTION WHEN WALKING	11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Diagnosis/Procedure 5	SHORTNESS OF BREATH UPON EXERTION WHEN WALKING	10-MAR-2010 09:58:32	Data Entry Error Amanda Lynn
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Diagnosis/Procedure 5	<Row Deleted>	12- >11;11- >10;10- >9;9- >8;8- >7;7- >6;6->5	24-MAR-2010 15:31:59 Data Entry Error Kryisia Magnuson
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Ongoing 5	CHECKED	11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Ongoing 5	CHECKED	10-MAR-2010 09:58:32	Data Entry Error Amanda Lynn
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Ongoing 5	<Row Deleted>	12- >11;11- >10;10- >9;9- >8;8- >7;7- >6;6->5	24-MAR-2010 15:31:59 Data Entry Error Kryisia Magnuson
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Sequence Number 5	05	11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Sequence Number 5	05	10-MAR-2010 09:58:32	Data Entry Error Amanda Lynn
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Document #: R243911113

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

Sequence Number 5	<Row Deleted>	12- >11;11- >10;10- >9;9- >8;8- >7;7- >6;6->5	24-MAR-2010 15:31:59	Data Entry Error Kryisia Magnuson
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Sequence Number 5	06 05		10-MAR-2010 09:59:49	Data Entry Error Amanda Lynn
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Date of Onset 6	00-00-2000		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Date of Resolution 6			11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Diagnosis/Procedure 6	RESPIRATORY BRONCHIAL INTERSTITIAL		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Ongoing 6	CHECKED		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Sequence Number 6	06		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Sequence Number 6	07 06		10-MAR-2010 09:59:49	Data Entry Error Amanda Lynn
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Date of Onset 7	00-00-1995		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Date of Resolution 7			11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Diagnosis/Procedure 7	DIABETES TYPE II		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Diagnosis/Procedure 7	HEARBURN HEARTBURN		24-FEB-2010 14:17:43	ODM/SEC Kryisia Magnuson Hearburn to Heartburn.
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Ongoing 7	CHECKED		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Sequence Number 7	07		11-JUN-2009 14:39:10	Row Inserted Amanda Lynn
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Document #: R243911113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Screening	Page_09 09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	9	Screening

<b>Group #</b>	<b>Group Name</b>
2	MH1

Sequence Number	08	10-MAR-2010 09:59:49	Data Entry Error
7	07	Amanda Lynn	

Date of Onset		11-JUN-2009 14:39:10	Row Inserted
8	00-00-1985	Amanda Lynn	

Date of Resolution		11-JUN-2009 14:39:10	Row Inserted
8		Amanda Lynn	

Diagnosis/Procedure		11-JUN-2009 14:39:10	Row Inserted
8	HEARBURN	Amanda Lynn	

Diagnosis/Procedure	GASTRO ESOPHAGEAL REFLUX DISEASE	24-FEB-2010 14:10:24	ODM/SEC
8	GASTROESOPHAGEAL REFLUX DISEASE	Kryisia Magnuson	Gastro esophageal to Gastroesophageal.

Ongoing		11-JUN-2009 14:39:10	Row Inserted
8	CHECKED	Amanda Lynn	

Sequence Number		11-JUN-2009 14:39:10	Row Inserted
8	08	Amanda Lynn	

Sequence Number	09	10-MAR-2010 09:59:49	Data Entry Error
8	08	Amanda Lynn	

Date of Onset		11-JUN-2009 14:39:10	Row Inserted
9	00-00-1985	Amanda Lynn	

Date of Resolution		11-JUN-2009 14:39:10	Row Inserted
9		Amanda Lynn	

Diagnosis/Procedure		11-JUN-2009 14:39:10	Row Inserted
9	GASTRO ESOPHAGEAL REFLUX DISEASE	Amanda Lynn	

Ongoing		11-JUN-2009 14:39:10	Row Inserted
9	CHECKED	Amanda Lynn	

Sequence Number		11-JUN-2009 14:39:10	Row Inserted
9	09	Amanda Lynn	

Sequence Number	10	10-MAR-2010 09:59:49	Data Entry Error
9	09	Amanda Lynn	

Date of Onset		11-JUN-2009 14:39:10	Row Inserted
10	00-00-1981	Amanda Lynn	

**Document #:** R243911113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Screening	Page_09 09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	9	Screening

<b>Group #</b>	<b>Group Name</b>
2	MH1

Date of Resolution 10		11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Diagnosis/Procedure 10	ANEMIA	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Ongoing 10	CHECKED	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Sequence Number 10	10	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Sequence Number 10	11 10	10-MAR-2010 09:59:49 Amanda Lynn	Data Entry Error
Date of Onset 11	00-00-1999	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Date of Resolution 11		11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Diagnosis/Procedure 11	SEASONAL ALLERGIES	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Ongoing 11	CHECKED	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Sequence Number 11	11	11-JUN-2009 14:39:10 Amanda Lynn	Row Inserted
Sequence Number 11	12 11	10-MAR-2010 09:59:49 Amanda Lynn	Data Entry Error
Date of Onset 12	00-FEB-2004	12-JAN-2010 13:04:27 Amanda Lynn	Row Inserted
Date of Resolution 12		12-JAN-2010 13:04:27 Amanda Lynn	Row Inserted
Diagnosis/Procedure 12	DIABETIC NEUROPATHY	12-JAN-2010 13:04:27 Amanda Lynn	Row Inserted
Ongoing 12	CHECKED	12-JAN-2010 13:04:27 Amanda Lynn	Row Inserted

**Document #:** R243911113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Screening	Page_09 09

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Mh	Page number	9	Screening

<b>Group #</b>	<b>Group Name</b>
2	MH1

Sequence Number	12	12-JAN-2010 13:04:27	Row Inserted
12	12	Amanda Lynn	

Document #: R243394013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Screening	Page_10 10

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Smoking History	Page number	10	Screening

<b>Group #</b>	<b>Group Name</b>
1	DRUGSCR

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Attempted to quit (Other cessation aids) (4) 1	YES NO	29-JUL-2009 15:36:24 Amanda Lynn	Data Entry Error
Attempted to quit (Pharmaceuticals) (3) 1	NO YES	29-JUL-2009 15:36:24 Amanda Lynn	Data Entry Error
Comments (other cessation aids) (6) 1	CHANTIX ONCE 2008 AND WELLBURTIN ONCE 2007	29-JUL-2009 15:36:24 Amanda Lynn	Data Entry Error
Comments (pharmaceuticals) (5) 1	CHANTIX ONCE 2008 AND WELLBURTIN ONCE 2007	29-JUL-2009 15:36:24 Amanda Lynn	Data Entry Error
Comments (pharmaceuticals) (5) 1	CHANTIX ONCE 2008 AND WELLBURTIN ONCE 2007 CHANTIX ONCE 2008 AND WELLBUTRIN ONCE 2007	08-MAR-2010 13:28:11 Krysia Magnuson	ODM/SEC Wellburtin to Wellbutrin. KAY 08Mar2010.
Has subject used smokeless tobacco (1) 1	YES NO	29-JUL-2009 15:15:28 Amanda Lynn	Data Entry Error
If Yes, how many (other cessation aids) (5) 1	2	29-JUL-2009 15:36:24 Amanda Lynn	Data Entry Error
If Yes, how many (pharmaceuticals) (4) 1	2	29-JUL-2009 15:36:24 Amanda Lynn	Data Entry Error

**Document #:** R243395213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Screening	Page_11 11

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Oral Health Exam	Page number	11	Screening

<b>Group #</b>	<b>Group Name</b>
1	EX1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Findings* 3	NE NO	11-JUN-2009 14:37:57 Amanda Lynn	Data Entry Error

**Document #:** R243911613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Sptp, Weeks 1-4	Page_16 16

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	16B	Sptp, Weeks 1-4

<b>Group #</b>	<b>Group Name</b>
0	Section Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCM Blank flag 1	N Y	14-MAY-2009 08:37:01 Amanda Lynn	Key Change
DCM Blank flag 1	Y N	20-MAY-2009 14:45:01 Amanda Lynn	Data Entry Error

**Document #:** R260439013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Ip, Week 10	Page_24 24

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	24	Ip, Week 10

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	42 21	23-OCT-2009 14:28:29 Amanda Lynn	Data Entry Error

**Document #:** R266126613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Ip, Week 16	Page_31 31

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Status Review	Page number	31	Ip, Week 16

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
If Subject was not compliant, approximat (5) 1	63 14	23-OCT-2009 14:29:46 Amanda Lynn	Data Entry Error

**Document #:** R270723813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Fu, Week 20 & 24	Page_32 32

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

<b>Group #</b>	<b>Group Name</b>
1	CHKYN

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Comments (how many cigarettes) (5) 1	UNKNOWN DUE TO TELEPHONE CONTACT AND VISIT DO NOT MATCH UP.	27-JAN-2010 14:56:47 Amanda Lynn	Data Entry Error
Comments (how many cigarettes) (5) 1	UNKNOWN DUE TO TELEPHONE CONTACT AND VISIT DO NOT MATCH UP. UNKNOWN DUE TO TELEPHONE AND DIARY DO NOT MATCH UP.	27-JAN-2010 14:59:15 Amanda Lynn	Data Entry Error
Comments (how many cigarettes) (5) 1	UNKNOWN DUE TO TELEPHONE AND DIARY DO NOT MATCH UP.	05-MAR-2010 11:37:09 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	112 UNK	27-JAN-2010 14:56:47 Amanda Lynn	Data Entry Error
If Subject was not compliant, approximat (5) 1	UNK 112	05-MAR-2010 11:37:09 Amanda Lynn	Data Entry Error
Was Subject asked HDYF? (8) 1	YES 0	27-JAN-2010 14:59:49 Amanda Lynn	Data Entry Error

**Document #:** R279063913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Fu, Week 28	Page_37 37

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Questionnaires	Page number	37	Fu, Week 28

<b>Group #</b>	<b>Group Name</b>
1	EX1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
MNWS 1	YES NO	11-NOV-2009 14:23:46 Amanda Lynn	Data Entry Error
MNWS 1	NO YES	11-NOV-2009 14:24:06 Amanda Lynn	Data Entry Error

**Document #:** R243406213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Pcm.1	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.1

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Frequency 1	EVERY MORNING EVERY DAY	27-APR-2009 08:42:52 Amanda Lynn	Data Entry Error

**Document #:** R243406513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Pcm.2	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.2

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Frequency 1	EVERY MORNING EVERY DAY	27-APR-2009 08:43:04 Amanda Lynn	Data Entry Error

**Document #:** R243406913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Pcm.4	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.4

<b>Group #</b>	<b>Group Name</b>
1	CM1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Frequency 1	EVERY MORNING EVERY DAY	27-APR-2009 08:43:17 Amanda Lynn	Data Entry Error

Document #: R260440113

Patient Site	Visit Visit Date	CRF CRF Page
R2010 L0689282_2	Pcm.6	Page_39

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Pcm	Page number	39	Pcm.6

Group #	Group Name
1	CM1

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
Indication 1	DIABETES DIABETEC NEUROPATHY	12-JAN-2010 13:05:18 Amanda Lynn	Data Entry Error
Indication 1	DIABETEC NEUROPATHY DIABETIC NEUROPATHY	09-APR-2010 14:58:34 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 09Apr2010

Document #: R260435713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Additional Vs	Page_43 43

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	43	Additional Vs

<b>Group #</b>	<b>Group Name</b>
1	VS

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Body Temperature 1	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error
Diastolic Blood Pressure 1	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error
Respiratory Rate 1	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error
Systolic Blood Pressure 1	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error
Body Temperature 2	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error
Diastolic Blood Pressure 2	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error
Respiratory Rate 2	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error
Systolic Blood Pressure 2	NA ND	26-FEB-2010 14:59:32 Amanda Lynn	Data Entry Error

**Document #:** R279062913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R2010 L0689282_2	Additional Vs.1	Page_43

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Vs	Page number	43	Additional Vs.1

<b>Group #</b>	<b>Group Name</b>
1	VS

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Body Temperature 1	NA ND		26-FEB-2010 15:00:09 Amanda Lynn	Data Entry Error
Diastolic Blood Pressure 1	NA ND		26-FEB-2010 15:00:09 Amanda Lynn	Data Entry Error
Respiratory Rate 1	NA ND		26-FEB-2010 15:00:09 Amanda Lynn	Data Entry Error
Systolic Blood Pressure 1	NA ND		26-FEB-2010 15:00:09 Amanda Lynn	Data Entry Error

# Discrepancy Detail Report

Document #: R243394013

Discrepancy ID: 1688674413                      Site: L0689282\_2                      Patient: R2010  
Visit: SCREENING                      Visit Date:  
CRF: PAGE\_10                      Section: SMOKING HISTORY                      Qualifying Value: 10  
Field: Has subject used smokeless tobacco                      Row: 1  
Value Text: NO  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Should this be NO?  
Internal Comment:  
Resolution Type: No Action Required  
Resolution Text:

Discrepancy ID: 1688674313                      Site: L0689282\_2                      Patient: R2010  
Visit: SCREENING                      Visit Date:  
CRF: PAGE\_10                      Section: SMOKING HISTORY                      Qualifying Value: 10  
Field: If Yes, how many (other cessation aids)                      Row: 1  
Value Text:  
Type: MANUAL                      Status: CURRENT  
Review Status: Resolved-Response Edited  
Discrepancy: Please record Chantix and wellbutrin under pharmaceuticals  
Internal Comment:  
Resolution Type: Confirmed  
Resolution Text:



**Document #: R270723813**

**Discrepancy ID:** 77965111                      **Site:** L0689282\_2                      **Patient:** R2010

**Visit:** FU, WEEK 20 & 2    **Visit Date:**

**CRF:** PAGE\_32                      **Section:** STATUS REVIEW                      **Qualifying Value:** 32.1

**Field:** Comments (how many cigarettes)                      **Row:** 1

**Value Text:**

**Type:** MANUAL                      **Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Per CRF Completion Guidelines, telephone data should override diary data if they are conflicting. Please update Week 24 Result AND Comments according to phone data.

**Internal Comment:**

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

**Resolution Text:**

**Discrepancy ID:** 36516711                      **Site:** L0689282\_2                      **Patient:** R2010

**Visit:** FU, WEEK 20 & 2    **Visit Date:**

**CRF:** PAGE\_32                      **Section:** STATUS REVIEW                      **Qualifying Value:** 32.1

**Field:** If Subject was not compliant, approximat                      **Row:** 1

**Value Text:** 112

**Type:** MANUAL                      **Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify value as it is significantly more than other non-compliance responses for this subject.

**Internal Comment:**

I changed this back because a query was sent saying if the telephone and the diary conflicts then go by the telephone so that is what I did. Even though I had unknown there already. So please let me know if I should put it back to what I had before as unknown or leave it as 112.

**Resolution Type:** Confirmed

**Resolution Text:**

**Discrepancy ID:** 49569211                      **Site:** L0689282\_2                      **Patient:** R2010

**Visit:** FU, WEEK 20 & 2    **Visit Date:**

**CRF:** PAGE\_32                      **Section:** STATUS REVIEW                      **Qualifying Value:** 32.1

**Field:** Was Subject asked HDYF?                      **Row:** 1

**Value Text:** 0

**Type:** UNIVARIATE                      **Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Value of 0 for Was Subject asked HDYF? not found in YES,NO

**Internal Comment:**

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

**Resolution Text:**

**Document #: R279064413**

**Discrepancy ID:** 36536411

**Site:** L0689282\_2

**Patient:** R2010

**Visit:** FU, WEEK 28

**Visit Date:**

**CRF:** PAGE\_38

**Section:** STATUS REVIEW

**Qualifying Value:** 38

**Field:** If Subject was not compliant, approximat

**Row:** 1

**Value Text:** 28

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please verify number smoked.

**Internal Comment:** per diary it is 28 please explain?

**Resolution Type:** No Action Required

**Resolution Text:**

**Document #: R243405513**

**Discrepancy ID:** 98519411

**Site:** L0689282\_2

**Patient:** R2010

**Visit:** PCM

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Start Date

**Row:** 1

**Value Text:** 1979

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Anema MH start date is 1981. Please verify and update start date of medication and/or MH.

**Internal Comment:** correct as is.

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R260440113**

**Discrepancy ID:** 36544611

**Site:** L0689282\_2

**Patient:** R2010

**Visit:** PCM.6

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Indication

**Row:** 1

**Value Text:** DIABETIC NEUROPATHY

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please confirm indication of con-med. Is the med given for depression related to diabetes? Please have staff and investigator review source and contact subject if necessary.

**Internal Comment:** updated conmed

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

**Resolution Text:**

# Deleted CRFs Report