

# CRF Report for Study E7694105

Report run by Brian Saari at 05-MAR-2013 12:21:32

## Report Parameters

Site: P3880\_0342

Discrepancy status choice: All statuses

Approval status choice: All statuses

Verification status choice: All statuses

Starting patient: R4120

Ending patient: R4120

### 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

Visit Name

Subject Number

Subject Initials

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Inclusion Criteria

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

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

\* If No, document on Subject Eligibility Page.

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

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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

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Information Session

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

Subject Eligibility

Date the Subject Signed the Informed Consent Form:

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

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

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Demographics

Date	Date of Birth	Gender	Ethnicity
<input type="text" value="20-JUL-2009"/>	<input type="text" value="(b) (6)"/>	<input type="checkbox"/> Male	<input type="checkbox"/> Hispanic or Latino
		<input checked="" type="checkbox"/> Female	<input checked="" type="checkbox"/> Not Hispanic or latino
Race			
<input checked="" type="checkbox"/> White	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander		
<input type="checkbox"/> Black or African American	<input type="checkbox"/> American Indian/Alaskan Native		
<input type="checkbox"/> Asian	<input type="checkbox"/> Other		<input type="text"/>

---

Body Measurements

Were Body Measurements Collected?  Yes  No

Date

Parameter	Unit	Result
Height	<input type="text" value="IN"/>	<input type="text" value="64.5"/>

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	120
Diastolic Blood Pressure	MMHG	70
Heart Rate	BEATS/MINUTE	65
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.0
Weight	LB	147.0

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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

Is Blank

12-Lead Electrocardiogram Report

Was ECG Performed?	Was Subject Supine at	Date	Actual Time
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Least 5 Minutes?	<input type="text" value="20-JUL-2009"/>	<input type="text" value="10:25"/>
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

ECG Interpretation

Normal  Abnormal, NCS  Abnormal, CS

Comments Regarding CS Findings:

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Swedish Match AB

Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Medical History

Date

Does the subject have any relevant medical history?  Yes  No

Sequence

Sequence No.	Diagnosis/Procedure	Date of Onset	Date of Resolution	
1	HYPOTHYROIDISM	00-00-2001		<input checked="" type="checkbox"/> Ongoing
2	OCCASIONAL SINUS HEADACHE	UNK		<input checked="" type="checkbox"/> Ongoing
3	OSTEOPENIA	00-00-2007		<input checked="" type="checkbox"/> Ongoing
4	MENOPAUSAL SYMPTOMS	00-00-1999		<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
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing
				<input type="checkbox"/> Ongoing

Consider the following systems when performing the assessment:

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Smoking History

Was Smoking History collected?

Yes  No

Date

Parameter	Result	Comments
Age subject began smoking daily	<input type="text" value="21"/>	
Average number of cigarettes smoked per day over the past year	<input type="text" value="20"/>	
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 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="3"/>	ON OWN DUE TO PREGNANCY

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Protocol Number: SM 08-01

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Visit Name

Subject Number

Subject Initials

Is Blank

Oral Health Examination

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

\* Indicate NE if system was not examined.

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

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Visit Name

Subject Number

Subject Initials

Is Blank

### Behavioral Counseling

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

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Expired Carbon Monoxide

Date	Actual Time	ECO Level ppm	%COHb	Comments
23-JUL-2009	15:33	17	3.3	

Behavioral Counseling

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

Questionnaires

Date

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

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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

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Diary Distribution

Date  Did subject receive diary and usage instructions?  
 Yes  No

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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Status Review

Date	Scheduled Timepoint	Parameter	Result	Comments
<input type="text" value="30-JUL-2009"/>	<input type="text" value="WEEK 1"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="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-AUG-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="35"/>	<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-AUG-2009"/>	<input type="text" value="WEEK 3"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
		Approximately how many cigarettes did the subject smoke that week?	<input type="text" value="28"/>	<input type="text"/>
		Was Behavioral Counseling Given?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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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-AUG-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="2"/>	<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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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	59
Heart Rate	BEATS/MINUTE	62
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.1
Weight	LB	148.6

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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-SEP-2009	10:16	3	1.1	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="02-SEP-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="7"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date	Did subject receive diary and usage instructions?
<input type="text" value="02-SEP-2009"/>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="17-SEP-2009"/>	Was Subject contacted by telephone?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input 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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Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	107
Diastolic Blood Pressure	MMHG	57
Heart Rate	BEATS/MINUTE	58
Respiratory Rate	BREATHS/MINUTE	12
Body Temperature	C	36.7
Weight	LB	147.2

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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-OCT-2009	11:26	9	2.0	

Behavioral Counseling

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

Questionnaires

Date

Questionnaire Was Questionnaire Administered?  
MNWS  Yes  No

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

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

Status Review

Date	Parameter	Result	Comments
<input type="text" value="01-OCT-2009"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject's use of study product reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input 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="35"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

Diary Distribution

Date  Did subject receive diary and usage instructions?  Yes  No

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Page Version No. PAGE\_24 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text"/>	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		
Diastolic Blood Pressure		
Heart Rate		
Respiratory Rate		
Body Temperature		
Weight		

Verified  Approved  Locked  Frozen

Page Version No. PAGE\_26 (v1, 27-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Laboratory Evaluations

Date

Were the scheduled laboratory samples obtained?

Yes

No (Specify samples not done, reason):

Evaluations: Biomarker Blood Tests

Requisition Number 1:

Requisition Number 2 (if applicable):

Requisition Number 3 (if applicable):

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

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

Note: Attach copy of signed laboratory report.

Verified  Approved  Locked  Frozen

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

Document Number

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

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

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\_28 (v1, 25-MAR-2009)

Document Number

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

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



## **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

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

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Page Version No. PAGE\_30 (v1, 31-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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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Page Version No. PAGE\_31 (v1, 12-MAY-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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="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"/>

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="28"/>	<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\_32 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Vital Signs

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

Parameter	Unit	Result
Systolic Blood Pressure	MMHG	99
Diastolic Blood Pressure	MMHG	48
Heart Rate	BEATS/MINUTE	61
Respiratory Rate	BREATHS/MINUTE	16
Body Temperature	C	37.0
Weight	LB	146.6

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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

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

\* Indicate NE if system was not examined.

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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
05-FEB-2010	09:09	14	3.0	

Behavioral Counseling

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

Questionnaires

Date

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

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Page Version No. PAGE\_37 (v1, 31-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Status Review

Date	Parameter	Result	Comments
<input type="text" value="05-FEB-2010"/>	Was Subject's smoking status reviewed?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>
	Was Subject compliant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="text"/>
	If Subject was not compliant, approximately how many cigarettes did the subject smoke that week?	<input type="text" value="UNK"/>	<input type="text"/>
	Was Subject asked HDYF? question?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>

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Page Version No. PAGE\_38 (v1, 27-MAR-2009)

Document Number

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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## **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 R4120

Covance Study Number: 7694-105

Subject Initials (b)

Visit Name PCM

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: FEMCREME

Indication: ESTROGEN REPLACEMENT THERAPY

Dose: 1

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

DIME SIZE CREAM

21 DAYS A MONTH

Start Date1

Stop Date1

00-00-1999

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

Document Number R289798913

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Document Number

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Subject Number

Covance Study Number: 7694-105

Subject Initials

Visit Name

Is Blank

Previous and Concomitant Medications

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

Yes, list below.  No

Drug Name:

Indication:

Dose:

Unit: Select only one

Frequency Select only one

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

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

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

Start Date1

Stop Date1

Ongoing

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

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Page Version No. PAGE\_39 (v1, 25-MAR-2009)

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

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Adverse Events

Did the subject experience any adverse events?  Yes  No

Adverse Event:

Onset Date

Onset Time

Resolved Date

Resolved Time   Ongoing

Serious Event: Select only one

- Yes
- No

Severity: Select only one

- Mild
- Moderate
- Severe

Relationship Select only one

- to Date:
- Not Related
  - Unlikely
  - Possibly Related
  - Probably Related
  - Definitely Related

Action Taken: Select only one

- None
- Other Drug Therapy, Specify as Con. Med.
- Other Treatment or Procedure, Specify:
- Discontinuation from Study
- Discontinuation of Drug Therapy

Outcome to Date Select only one

- Recovered
- Continuing without Treatment
- Continuing with Treatment
- Death

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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:
20-JUL-2009	10:25	<input type="checkbox"/> Normal <input checked="" type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	
		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	
		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	
		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	
		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, NCS <input type="checkbox"/> Abnormal, CS	

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Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

Additional Assessments - 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
20-NOV-2009	NA	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			
		<input type="checkbox"/> Yes <input type="checkbox"/> No			

Note: Attach copy of signed laboratory report.

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Page Version No. PAGE\_42 (v1, 27-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

Covance Study Number: 7694-105

Visit Name

Subject Number

Subject Initials

Is Blank

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	101
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	53
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	ND
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	ND
	Body Temperature	C	ND

Comments

Date  Actual Time

Position	Parameter	Unit	Result
<input type="checkbox"/> Standing	Systolic Blood Pressure	MMHG	104
<input type="checkbox"/> Supine	Diastolic Blood Pressure	MMHG	54
<input checked="" type="checkbox"/> Seated	Heart Rate	BEATS/MINUTE	68
<input type="checkbox"/> Other, specify <input type="text"/>	Respiratory Rate	BREATHS/MINUTE	16
	Body Temperature	C	36.6

Comments

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Page Version No. PAGE\_43 (v1, 27-MAR-2009)

Document Number

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

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



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

\* Indicate NE if system was not examined.

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Page Version No. PAGE\_45 (v1, 25-MAR-2009)

Document Number

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

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

Swedish Match AB

Protocol Number: SM 08-01

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.

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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 #:** R289779313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Screening	Page_05 05

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Dm	Page number	5	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Age 1	50 49		31-MAR-2010 12:25:13 Lana Glaser	Derivation
Date of Birth 1	09-JUL-1959 07-SEP-1959		31-MAR-2010 12:23:36 Lana Glaser	Data Entry Error

**Document #:** R289779313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Screening	Page_05 05

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Bm	Page number	5	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date 1	09-JUL-1959 20-JUL-2009	25-JAN-2010 12:01:10 Kim Freschly	Data Entry Error

**Document #:** R289780313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Screening	Page_07 07

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Lb	Page number	7	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date 1	25-JAN-2010 20-JUL-2009	24-MAR-2010 10:57:03 Kim Freschly	Data Entry Error

**Document #:** R289780913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Screening	Page_08 08

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Eg	Page number	8	Screening

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Date 1	25-JAN-2010 20-JUL-2009	10-MAR-2010 09:33:12 Kim Freschly	Data Entry Error

**Document #:** R289783413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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	00-00-2001	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Date of Resolution 1		10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Diagnosis/Procedure 1	HYPOTHYROIDISM	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Does the subject have any relevant medication 1	YES	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Ongoing 1	CHECKED	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Sequence Number 1	1	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Date of Onset 2	UNK	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Date of Resolution 2		10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Diagnosis/Procedure 2	OCCASIONAL SINUS HEADACHE	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Ongoing 2	CHECKED	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Sequence Number 2	2	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Date of Onset 3	00-00-2007	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Date of Resolution 3		10-MAR-2010 09:37:54 Kim Freschly	Row Inserted

**Document #:** R289783413

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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

Diagnosis/Procedure 3	OSTEOPENIA	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Ongoing 3	CHECKED	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Sequence Number 3	3	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Date of Onset 4	00-00-1999	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Date of Resolution 4		10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Diagnosis/Procedure 4	MENOPAUSE	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Diagnosis/Procedure 4	MENOPAUSE MENOPAUSAL SYMPTOMS	17-MAR-2010 13:11:26 Lana Glaser	Data Entry Error
Ongoing 4	CHECKED	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted
Sequence Number 4	4	10-MAR-2010 09:37:54 Kim Freschly	Row Inserted

**Document #:** R289784213

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
R4120 P3880_0342	Screening	Page_12 12	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pe	Page number	12	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>
Does the subject have any abnormal findi 1	YES NO	25-JAN-2010 12:08:07 Kim Freschly	Data Entry Error

**Document #:** R289795813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ip, Week 10	Page_23 23

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Behavioral Coun	Page number	23	Ip, Week 10

<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>
Result 1	YES	25-JAN-2010 12:56:11 Kim Freschly	Data Entry Error

**Document #:** R289796313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ip, Week 16	Page_26 26

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	24-MAR-2010 10:57:47 Kim Freschly	Data Entry Error

**Document #:** R289796513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ip, Week 16	Page_27 27

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	24-MAR-2010 10:58:33 Kim Freschly	Data Entry Error

**Document #:** R289796613

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ip, Week 16	Page_28 28

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	24-MAR-2010 10:58:41 Kim Freschly	Data Entry Error

**Document #:** R289796813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ip, Week 16	Page_29 29

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	24-MAR-2010 10:58:53 Kim Freschly	Data Entry Error

**Document #:** R289796913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ip, Week 16	Page_30 30

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	24-MAR-2010 10:59:02 Kim Freschly	Data Entry Error

**Document #:** R289797513

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ip, Week 16	Page_31 31

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
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<b>Group #</b>	<b>Group Name</b>
0	CRF Header

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
DCI Blank Flag 1	N Y	24-MAR-2010 10:59:08 Kim Freschly	Data Entry Error

**Document #:** R289798113

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Pcm	Page_39 39

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

<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>
Indication 1	THYROID/GOITER HYPOTHYROIDISM	10-MAR-2010 09:43:47 Kim Freschly	Data Entry Error

**Document #:** R289798713

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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 DAY EVERY WEEK	10-MAR-2010 09:44:05 Kim Freschly	Data Entry Error

Document #: R289798913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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>
ATC1 Code 1	G	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC1 Text 1	GENITO URINARY SYSTEM AND SEX HORMONES, G	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Code 1	G03	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC2 Text 1	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, G03	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Code 1	G03D	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC3 Text 1	PROGESTOGENS, G03D	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Code 1	G03DA	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
ATC4 Text 1	PREGNEN (4) DERIVATIVES, G03DA	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Drug Modified Reported Term 1	FEM CREME FEMCREME	20-APR-2010 11:29:16 Carol Kraucyk	Data Change
Drug name 1	FEM CREME FEMCREME	12-APR-2010 12:40:34 Joanne Mccaigue	ODM/SEC Obvious spelling correction. JLM 12Apr2010
Preferred Term 1	PROGESTERONE	26-APR-2010 10:36:00 Carol Kraucyk	Data Change
Preferred Term Code 1	00110701001	26-APR-2010 10:36:00 Carol Kraucyk	Data Change

**Document #:** R289799913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Pcm.3	Page_39

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Pcm	Page number	39	Pcm.3

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

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on resequence</b>	<b>On By</b>	<b>Reason Comment</b>
Dose 1	UNK		10-MAR-2010 09:45:40 Kim Freschly	Data Entry Error
Unit 1	OTHER		13-APR-2010 10:58:30 Lana Glaser	Data Entry Error
other, specify (unit) 1	UNKNOWN		13-APR-2010 10:58:30 Lana Glaser	Data Entry Error

**Document #:** R289801013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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>
ATC1 Code 1	C	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC1 Code 1	C M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC1 Text 1	CARDIOVASCULAR SYSTEM, C MUSCULO-SKELETAL SYSTEM, M	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Code 1	C01	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC2 Code 1	C01 M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC2 Text 1	CARDIAC THERAPY, C01	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC2 Text 1	CARDIAC THERAPY, C01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, M01	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Code 1	C01E	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC3 Code 1	C01E M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC3 Text 1	OTHER CARDIAC PREPARATIONS, C01E ANTIINFLAMMATORY/ANTIRHE UMATIC PROD.,NON- STEROIDS, M01A	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
ATC4 Code 1	C01EB	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC4 Code 1	C01EB M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change

**Document #:** R289801013

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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

ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
ATC4 Text 1	OTHER CARDIAC PREPARATIONS, C01EB PROPIONIC ACID DERIVATIVES, M01AE	27-APR-2010 12:10:38 Joanne Mccaigue	Data Change
Dose 1	200 400	10-MAR-2010 09:46:21 Kim Freschly	Data Entry Error
Preferred Term 1	IBUPROFEN	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
Preferred Term Code 1	00109201001	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
Trade Name 1	ADVIL /00109201/	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change
Trade Name Code 1	00109201030	20-APR-2010 11:29:16 Carol Kraucyk	Class. Change

**Document #:** R289801313

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	Ae	Page_40 40

<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Ae	Page number	40	Ae

<b>Group #</b>	<b>Group Name</b>
1	AE1

<b>Field Row</b>	<b>Changed From Changed To</b>	<b>Impact on On resequence By</b>	<b>Reason Comment</b>
Resolved Time 1	UNK 0900	17-MAR-2010 08:55:21 Lana Glaser	Data Entry Error

Document #: R297617613

Patient Site	Visit Visit Date	CRF CRF Page
R4120 P3880_0342	Additional Lab	Page_42 42

Section Section Date	Qualifying Prompt	Qualifying Value	Section Visit
Lb	Page number	42	Additional Lab

Group #	Group Name
1	LB

Field Row	Changed From Changed To	Impact on resequence	On By	Reason Comment
Clinically Significant (additional) (2) 1	NO		24-MAR-2010 11:00:04 Kim Freschly	Row Inserted
Comments 1			24-MAR-2010 11:00:04 Kim Freschly	Row Inserted
Date 1	20-NOV-2009		24-MAR-2010 11:00:04 Kim Freschly	Row Inserted
Requisition Number (additional labs) (4) 1	NA		24-MAR-2010 11:00:04 Kim Freschly	Row Inserted
Test Code ID CS Labs only 1			24-MAR-2010 11:00:04 Kim Freschly	Row Inserted
Test Name CS Labs only 1			24-MAR-2010 11:00:04 Kim Freschly	Row Inserted
Were any additional Laboratory evaluatio 1	NO YES		24-MAR-2010 11:00:04 Kim Freschly	Data Entry Error

Document #: R297616913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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>
Actual Time 2	1042	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Body Temperature 2	36.6	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Body Temperature Unit 2	C	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Comments (2) 2		24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Date 2	20-NOV-2009	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Diastolic Blood Pressure 2	54	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Diastolic Blood Pressure unit 2	MMHG	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Heart Rate 2	68	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Heart Rate Unit 2	BEATS/MINUTE	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Other, specify (1) 2		24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Position (Unscheduled) (2) 2	SEATED	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Respiratory Rate 2	16	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted
Respiratory Rate Unit 2	BREATHS/MINUTE	24-MAR-2010 11:00:25 Kim Freschly	Row Inserted

**Document #:** R297616913

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>
R4120 P3880_0342	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

Systolic Blood Pressure 2	104	24-MAR-2010 11:00:25	Row Inserted Kim Freschly
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Systolic Blood Pressure unit 2	MMHG	24-MAR-2010 11:00:25	Row Inserted Kim Freschly
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Document #: R297617713

Patient Site	Visit Visit Date	CRF CRF Page
R4120 P3880_0342	Additional Pe	Page_44 44

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

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	Y N	24-MAR-2010 11:00:53 Kim Freschly	Data Entry Error

Document #: R297617813

Patient Site	Visit Visit Date	CRF CRF Page
R4120 P3880_0342	Oral Health Exam	Page_45 45

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

Field Row	Changed From Changed To	Impact on On resequence By	Reason Comment
DCI Blank Flag 1	Y N	24-MAR-2010 11:01:11 Kim Freschly	Data Entry Error

**Document #:** R297617813

<b>Patient Site</b>	<b>Visit Visit Date</b>	<b>CRF CRF Page</b>	
R4120 P3880_0342	Oral Health Exam	Page_45 45	
<b>Section Section Date</b>	<b>Qualifying Prompt</b>	<b>Qualifying Value</b>	<b>Section Visit</b>
Oral Health Exam	Page number	45	Oral Health Exam

<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>
Date 3	20-NOV-2009	24-MAR-2010 11:01:22 Kim Freschly	Data Entry Error





**Document #: R289780913**

**Discrepancy ID:** 64052911

**Site:** P3880\_0342

**Patient:** R4120

**Visit:** SCREENING

**Visit Date:**

**CRF:** PAGE\_08

**Section:** EG

**Qualifying Value:** 8

**Field:** Date

**Row:** 1

**Value Text:** 20090720

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Per source this looks like 20Jul09; please consult source and confirm or correct as appropriate. Thank you!

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R289783413**

**Discrepancy ID:** 85947311                      **Site:** P3880\_0342                      **Patient:** R4120  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_09                      **Section:** MH                      **Qualifying Value:** 9  
**Field:** Diagnosis/Procedure                      **Row:** 4  
**Value Text:** MENOPAUSAL SYMPTOMS  
**Type:** MANUAL                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify menopause should be deleted.  
**Internal Comment:** left on med hx per PI  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Discrepancy ID:** 76431411                      **Site:** P3880\_0342                      **Patient:** R4120  
**Visit:** SCREENING                      **Visit Date:**  
**CRF:** PAGE\_09                      **Section:** MH                      **Qualifying Value:** 9  
**Field:**                      **Row:**  
**Value Text:**  
**Type:** MANUAL HEADER                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please complete this page; source is complete.  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Document #: R289798713**

**Discrepancy ID:** 64059311

**Site:** P3880\_0342

**Patient:** R4120

**Visit:** PCM.1

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:** Frequency

**Row:** 1

**Value Text:** EVERY WEEK

**Type:** MANUAL

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please confirm if this is every day or 3X per week; verify and confirm or correct. Thank you!

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

**Document #: R289799913**

**Discrepancy ID:** 99129711

**Site:** P3880\_0342

**Patient:** R4120

**Visit:** PCM.3

**Visit Date:**

**CRF:** PAGE\_39

**Section:** PCM

**Qualifying Value:** 39

**Field:**

**Row:**

**Value Text:**

**Type:** MANUAL HEADER

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please check 'other, specify' and specify 'UNK' if unit is unknown.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:** Verified. JLM 21Apr2010

**Document #: R289801013**

**Discrepancy ID:** 64059711                      **Site:** P3880\_0342                      **Patient:** R4120  
**Visit:** PCM.4                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Dose    **Row:** 1  
**Value Text:** 400  
**Type:** MANUAL    **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Per update to source, please verify this amount of Advil based on footnote.  
**Internal Comment:** Per source/footnote the subject took 2 tablets = 400 mg.  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 99129811                      **Site:** P3880\_0342                      **Patient:** R4120  
**Visit:** PCM.4                      **Visit Date:**  
**CRF:** PAGE\_39                      **Section:** PCM                      **Qualifying Value:** 39  
**Field:** Indication    **Row:** 1  
**Value Text:** GENERAL ACHES AND PAINS  
**Type:** MANUAL    **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** General aches and pains is not captured on medical history. Please verify adding.  
**Internal Comment:** per PI subject's history of general aches and pain is not relevant to study  
**Resolution Type:** Confirmed  
**Resolution Text:** Verified. JLM 21Apr2010

**Document #: R289801313**

**Discrepancy ID:** 64058411                      **Site:** P3880\_0342                      **Patient:** R4120  
**Visit:** AE                      **Visit Date:**  
**CRF:** PAGE\_40                      **Section:** AE                      **Qualifying Value:** 40  
**Field:**    **Row:**  
**Value Text:**  
**Type:** MANUAL HEADER                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Per source, there was not action taken; please confirm and complete as appropriate.  
**Internal Comment:**  
**Resolution Type:** Confirmed  
**Resolution Text:**

**Discrepancy ID:** 85955611                      **Site:** P3880\_0342                      **Patient:** R4120  
**Visit:** AE                      **Visit Date:**  
**CRF:** PAGE\_40                      **Section:** AE                      **Qualifying Value:** 40  
**Field:**    **Row:**  
**Value Text:**  
**Type:** MANUAL HEADER                      **Status:** CURRENT  
**Review Status:** Resolved-Response Edited  
**Discrepancy:** Please verify time per source.  
**Internal Comment:**  
**Resolution Type:** Data value changed. Disc no longer applicable.  
**Resolution Text:**

**Document #: R289783213**

**Discrepancy ID:** 76432811

**Site:** P3880\_0342

**Patient:** R4120

**Visit:** ADDITIONAL ECG

**Visit Date:**

**CRF:** PAGE\_41

**Section:** EG

**Qualifying Value:** 41

**Field:**

**Row:**

**Value Text:**

**Type:** MANUAL HEADER

**Status:** CURRENT

**Review Status:** Resolved-Response Edited

**Discrepancy:** Please complete page; there are no additional ECGs.

**Internal Comment:**

**Resolution Type:** Confirmed

**Resolution Text:**

# Deleted CRFs Report